EXHIBIT 2

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804
This document relates to: Case Track 13: *Lincoln County v. Richard Sackler, M.D. et al*, Case No. 20-op-45069	Case No. 17-md-2804 Judge Dan Aaron Polster

PLAINTIFF LINCOLN COUNTY, MISSOURI'S SUPPLEMENTAL AND AMENDED ALLEGATIONS TO BE ADDED TO THE COMPLAINT
(Jury Trial Demanded)

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Plaintiff Lincoln County, Missouri, by and through the undersigned attorneys ("Plaintiff") hereby supplements and amends its Complaint, dated October 24, 2019 (Doc. No. 1) in this action against Defendants Express Scripts, Inc., Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Order Processing, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., Evernorth Health, Inc. (formerly Express Scripts Holding Company), and Express Scripts Specialty Distribution Services, Inc. (collectively, "Express Scripts"); and UnitedHealth Group, Inc., Optum, Inc., OptumInsight, Inc., OptumInsight Life Sciences, Inc., OptumRx, Inc., OptumRx Discount Card Services, LLC; Optum Perks, LLC; OptumHealth Care Solutions, LLC; OptumHealth Holdings, LLC; and Optum Health Networks, Inc., (collectively "Optum").[1] Together Express Scripts and Optum are referred to herein as "Defendants" or "the PBM Defendants."

In addition to the allegations set forth herein, Plaintiff expressly adopts and incorporates by reference the allegations and claims set forth in its Complaint (Doc. No.1), including all claims and allegations against other Defendants named in that Second Amended Complaint.

Lincoln County alleges as follows:

[1] The newly added defendants in this pleading are: Express Scripts Administrators, LLC; Medco Health Solutions, Inc.; ESI Mail Order Processing, Inc.; Express Scripts Specialty Distribution Services, Inc.; ESI Mail Pharmacy Service, Inc.; OptumInsight, Inc.; OptumInsight Life Sciences, Inc.; Optum Discount Card Services, LLC; Optum Perks, LLC; OptumHealth Care Solutions, LLC; OptumHealth Holdings, LLC; and Optum Health Networks, Inc. Additionally, Defendant Express Scripts Holding Company is now known as Evernorth Health, Inc.

I. Introduction

1. This case arises from a devastating epidemic of human creation—the over-prescription, over-supply, misuse, diversion, and abuse of opioids—and the central role that two of the nation's largest Pharmacy Benefit Managers ("PBMs"), Express Scripts and OptumRx, and their affiliates, have played in that epidemic.[2]

2. The opioid epidemic was created and sustained by a wide array of actors in the opioid supply and payment chain: the opioid manufacturers, distributors, and pharmacies, as well as by the PBM Defendants. Express Scripts' and Optum's role in stoking the opioid epidemic has been, until recently, largely concealed from public scrutiny. It is has now become clear that the PBM Defendants have, for at least the last two decades, had a central role in facilitating the oversupply of opioids through conduct that has the intended purpose of ignoring necessary safeguards for purposes of increasing the prescribing, dispensing and sales of prescription opioids. These defendants intentionally inserted themselves into the chain of distribution and dispensing of prescription opioids thereby assuming duties to act reasonably while comporting with the CSA.

3. The PBM Defendants sit at the center of prescription drug dispensing because they contract with the manufacturers who make the drugs, the pharmacies who dispense them, and the third-party payors who pay for them. The PBM

[2] In its Order Concerning the PBM Bellwether Process, dated October 27, 2023 (MDL Doc. No. 5231), the Court ordered that four bellwether cases would proceed only against the Optum and Express Scripts Defendant Families. Accordingly, Plaintiff addresses these supplemental and amended allegations only to those defendants.

Defendants' conduct that drove the increases and led to oversupply included: (a) colluding with, and aiding and abetting, Purdue Pharma and other opioid manufacturers in the fraudulent and deceptive marketing and oversupply of opioids; (b) colluding with Purdue Pharma and other opioid manufacturers to increase opioid sales through favorable placement on national formularies in exchange for rebates and fees; (c) colluding with Purdue Pharma and other opioid manufacturers to eliminate or limit utilization management measures on national formularies that would have restricted opioid prescribing; (d) deliberately failing properly and diligently to implement effective drug utilization review measures after undertaking to do; (e) electing not to act on the vast stores of information they had about the epidemic to limit the flood of opioids into communities across the United States, including Plaintiff's Community; and (f) dispensing huge quantities of prescription opioids through their mail-order pharmacies without proper controls against diversion, as required by the Controlled Substances Act and Missouri law.

4. The PBM Defendants are legally responsible for their role in causing, contributing to, and maintaining the opioid epidemic because, *inter alia*: (a) their conduct in colluding with the opioid manufacturers to increase the supply of opioids through false and fraudulent misrepresentations was intentional and/or negligent, and unlawful; (b) their knowing and/or negligent failure to offer formularies, utilization management protocols, and drug utilization review measures that would ensure safe and appropriate use of opioid medications was wrongful because they undertook to, and represented that they would, do so, but instead

worked with the opioid manufacturers to increase the supply of opioids without regard to the safety or appropriateness of the drugs; (c) they intentionally and/or negligently decided, acted, and continued to offer only formularies, utilization management protocols, and drug utilization measures that placed no meaningful restrictions on the prescribing and use of opioids despite knowing, through the vast stores of data they had, that (i) such unrestricted access to opioids was causing, and foreseeably would continue to cause, harm (including the foreseeable harm of diversion) to Plaintiffs' communities, and (ii) those harms could be addressed through measures that the PBM Defendants intentionally decided not to make available, (d) their conduct with respect to opioid prescribing and dispensing was unlawful as well as intentional and/or negligent because they failed to comply with the Controlled Substances Act and Missouri law, both in their own dispensing through their mail-order pharmacies and in their other activities that increased the risks of diversion; and (e) they unlawfully controlled association-in-fact enterprises with opioid manufacturers and others through a pattern of racketeering activity, as defined in the federal Racketeer-Influenced and Corrupt Organizations Act ("RICO").

5. The PBM Defendants' role in the opioid epidemic was made possible by their unique combination of knowledge and power that gave them an extraordinary ability to control the opioid supply throughout the United States.

6. One of the PBM Defendants' own executives recognized that no other actor in the healthcare system had a greater ability to affect the opioid crisis, boasting that "*[n]o component of our healthcare system is in a better position to deliver more*

immediate and more impactful changes to the current course of this crisis than our nation's PBMs…"[3]

7. The executive highlighted the PBMs' powerful position not only from an information perspective ("robust point-of-dispensing screening and intervention"), but also as "an intermediary between the physician, pharmacist, patient, pharmaceutical manufacturer, health systems, and other components of the industry," which situates the PBM Defendants "in an ideal position to drive improvements in education and awareness of the dangers of opioid therapy[.]"[4]

8. PBMs provide services to prescription drug benefit plans sponsored by health insurers, self-insured employers, and state and federal government agencies. The PBM Defendants collect and maintain (and sell) unprecedented amounts of data about the extent of opioid prescribing, far exceeding what any individual manufacturer, distributor, or pharmacy chain has access to. For as long as they have been PBMs, Express Scripts and Optum have received, analyzed, and tracked detailed claims data for the billions of prescriptions they process each year, including opioid prescriptions. Controlling prescription drug benefits for 160+ million Americans, the PBM Defendants are in possession of detailed information about every prescription they process, regardless of which company manufactured the drug, which doctor prescribed it, what pharmacy it was filled at, or which state it was dispensed in. They know when patients whose benefits they manage fill opioid

[3] OPTUMRX_JEFFCO_0000014980 (9/16/17) (emphasis added).

[4] *Id.*

prescriptions written by multiple doctors, and when they fill them at multiple pharmacies. They know how many times every opioid prescription they cover is refilled and they know when a patient who was prescribed opioids is later treated for substance use disorder. They know if one of their covered lives is having prescriptions filled for opioids, benzodiazepines, and sleep aids concurrently. In short, the PBM Defendants have had a unique vantage point on opioid use and prescribing patterns and associated misuse. These Defendants quite literally tracked the opioid epidemic, pill by pill, as it unfolded over the last two decades.

9. The PBM Defendants are not only in possession of massive amounts of information about opioid prescribing, they also have the power to encourage and/or drive prescribing, dispensing, and sales of prescription drugs.

10. The PBM Defendants are able to encourage and influence prescribing, dispensing, and sales primarily through the national formularies they offer to pharmacy benefit plans and through what they choose to offer in terms of standard "utilization management" ("UM") rules. Formularies are lists of drugs covered by a pharmacy benefit plan. Formularies control which drugs are available to the PBMs' covered lives. They are often constructed in tiers, where drugs listed on higher tiers require larger copays, or as so-called exclusionary formularies, where preferred brand drugs are included and nonpreferred drugs are not included. Standard UM programs include various protocols for managing access and use of particular drugs, including: (i) step therapy, where a beneficiary is required to try a different drug or therapy first before trying the restricted drug; (ii) quantity limits, which are limits on the dosage

or days' supply that a patient may receive for any given prescription(s); and (iii) prior authorizations, or ("PAs"), which are rules that require a physician to confirm that a given prescription is therapeutically appropriate before the drug is dispensed. Data shows that, when implemented, disfavored formulary placement and UM reduce inappropriate prescribing by making non-preferred drugs and/or drugs subject to UM restrictions more difficult and more costly to obtain. By contrast, the PBM Defendants and the opioid manufacturers knew that favorable formulary placement and the absence of UM restrictions create a scenario where prescriptions are written and dispensed with ease and frequency, at the expense of public safety.

11. Through their formulary and UM tools, and the other powers at their disposal, the PBM Defendants, in conjunction with opioid manufacturers, are and have been uniquely situated to influence and control the prescribing and dispensing of opioids to their 160+ million covered lives. Indeed, opioids that are preferred on PBM formularies have significantly greater sales than drugs that are either excluded or disadvantaged. In this sense, the PBM Defendants act as the gatekeepers to the opioid market.

12. The PBM Defendants have used their hugely profitable roles to grow into vertically integrated colossuses that have come to dominate access to prescription drugs—currently sitting at fifth (OptumRx) and twelfth (Express Scripts) on the Fortune 500 list ranking of the largest corporations in America by revenue. Defendant Express Scripts surpassed $100 billion of annual revenue as

early as 2017. Defendant OptumRx has also seen its revenue grow, reaching nearly $100 billion in 2022.

13. These two corporate leviathans are: (1) two of the three largest PBMs in the United States, collectively managing prescription drug coverage for 160+ million covered lives and processing more than 1.5 billion claims per year; (2) two of the top five dispensing pharmacies in the United States; (3) owned by two of the largest insurance companies in the world (UnitedHealth Group and Cigna); and (4) among the largest healthcare data, consulting, and analytics companies in the United States.

14. Instead of using their vast stores of information and extensive power to do what they promised their clients and represented to the public—*i.e.*, manage the floodgates of opioid prescribing and limit abuse of these dangerous drugs—the PBM Defendants worked together and with the opioid manufacturers to negotiate contracts and structure formulary and UM offerings that encouraged opioid prescribing, while facilitating easy and inexpensive dispensing and sales of those drugs. The result is that the market for prescription opioids grew, prescribing, dispensing and sales increased, and the PBM Defendants and opioid manufacturers reaped the profits of their contracts and relationships. For the PBM Defendants, the profits came from rebates and fees they earned from the branded opioid manufacturers by making opioids freely available and from pricing spreads and fees they captured from generic opioid sales. Profits also came through the sale of critical data and access to and about PBM covered lives and the health care providers who cared for them.

15. Not only did the PBM Defendants aid and abet the manufacturers through their pro-opioid formulary and UM offerings, they also colluded with the manufacturers in spreading fraudulent misrepresentations about the risks and benefits of opioids. The PBM Defendants fraudulently induced doctors to write more opioid prescriptions, and then they made sure it would be easy for patients to fill those prescriptions, thus ensuring an unfettered flow of opioids into communities across America.

16. The PBM Defendants' conduct represented a change of course. Prior to 1997, the PBM Defendants had recognized the dangers of opioids and had installed various routine controls on quantity and access. At that time, opioids were prescribed infrequently and generally only for either acute pain, calling for very short-term use, or for end-of-life cancer pain.

17. In the mid-1990's, Purdue Pharma ("Purdue") introduced OxyContin and began a campaign fraudulently to portray OxyContin as safe and effective for a variety of conditions, including chronic non-cancer pain calling for long-term use. Purdue set out to convince doctors, the medical establishment, and the public generally that opioids are not addictive when taken for pain, regardless of the dose or duration of the therapy. Over time, other opioid manufacturers introduced similar products, first branded opioid drugs and then generic ones, and joined in the campaign fraudulently to increase opioid prescribing.

18. OptumRx's predecessor Prescription Solutions initially refused to put OxyContin on its commercial formularies due to concerns regarding abuse.

19. Express Scripts' predecessor Medco, which was, in the late 1990's, the largest customer for Purdue's opioids, initially put a strict quantity limit (80 mg/day) on OxyContin when it was introduced in 1996 and sent letters to prescribers stating that it would not pay for prescriptions for non-cancer pain treatment ("Medco prescriber letters").

20. The Medco prescriber letters were a serious threat to Purdue and to other opioid manufacturers. The opioid manufacturers knew that they could not expand the opioid market and flood communities with their products without preferred, unrestricted access to their opioids on the PBM Defendants' formularies.

21. Recognizing the unique role that the PBM Defendants play as the gatekeepers of the pharmaceutical market, Purdue set out to change the PBM Defendants' policies about OxyContin and about opioids generally. Purdue did this not (or not primarily) by convincing the PBM Defendants that OxyContin was safe and effective for the treatment of chronic non-cancer pain—which it is not—but rather by convincing them that they could make vast amounts of money by allowing unrestricted access to opioids.

22. In a January 1997 email to Purdue's president Dr. Richard Sackler (and others) responding to the Medco prescriber letters, Michael Friedman, who would later become Purdue's CEO, stated, "This is a serious matter that we cannot ignore and that we must discuss. . . We cannot go on ignoring *the reality of [the PBM Defendants'] economic proof requirements* . . . If we are to stay in business we need *proof of economic performance*." (Emphasis added.) Purdue thus understood that for

OxyContin to succeed, it would have to show the PBM Defendants that increasing opioid use would be to their economic benefit.

23. This was a critical moment in the spread of the epidemic. If Medco—Purdue's largest customer—had excluded OxyContin from its formularies or restricted its use to palliative care and/or cancer pain in 1997 (as it should have), OxyContin would never have become widely available, other branded opioids and generics never would have followed the OxyContin wave, and the epidemic likely never would have happened.

24. Medco, however, failed to take such actions. Rather, Medco and the other PBM Defendants became knowing and willing partners with Purdue and the other opioid manufacturers at this critical juncture because they realized that increasing opioid use would indeed be profitable for them. The PBM Defendants were able to profit from such increased use because their agreements with the opioid manufacturers provided for rebates and "administrative fees" to be paid to the PBM Defendants for each rebate-eligible opioid prescription adjudicated by that PBM. Thus, every dollar spent on opioids would put money in the PBM Defendants' pockets. When a drug was given "preferred" status on a formulary, the rebates would be higher.

25. Within months of sending its prescriber letters warning about the dangers of OxyContin, Medco completely reversed course and informed Purdue that it had become "very interested in partnering with Purdue." Medco doubled its initial quantity limits from 80 mg/day to 160 mg/day within the first year of OxyContin's

release. By 2000, Medco again doubled this limit to 320 mg/day (*four times* the limit that Medco originally determined was medically appropriate for OxyContin). To make its formulary changes more effective, Medco worked "behind the scenes" with Purdue to persuade several of Medco's largest clients (including Optum's affiliate insurer UHC) to lift any restrictions they had (such as prior authorizations and quantity limits) on OxyContin sales.

26. But it wasn't enough for Medco to just lift restrictions on the filling of prescriptions (open the floodgates); it also worked with Purdue to increase the number of prescriptions being written (increase the flow of water at the source). To that end, it joined forces with Purdue on numerous marketing campaigns, assisting Purdue in its dissemination of fraudulent misrepresentations about the safety and efficacy of prescription opioids for a wide variety of conditions for which the drugs had previously been understood to be dangerous and unsuitable. This included mailings to prescribers fraudulently promoting OxyContin as safe and effective and only very rarely leading to abuse and/or addiction.

27. Medco was not alone. Abandoning their initial resistance to OxyContin, the other PBM Defendants quickly recognized the profit potential associated with it and began partnering with Purdue and other opioid manufacturers to expand the pain treatment market.

28. For years Express Scripts worked directly with Purdue to disseminate misinformation about OxyContin. These efforts included Express Scripts using its own "proprietary database" to locate high prescribers of opioids and then "blasting"

these physicians with materials created by Purdue-paid front groups that promoted myths about the use of opioids that they knew had no basis in fact. They did this to overcome the resistance doctors had to prescribing dangerous opioids. In a particularly telling exchange, Express Scripts informed Purdue that these efforts were necessary "so that [Express Scripts] may squelch the anti-OxyContin pushback from [Express Scripts] clients . . . due in large part to the [negative] national media attention OxyContin is receiving."[5]

29. OptumRx (then known as Prescription Solutions) initially excluded OxyContin from its formularies, but it reversed course and by the mid-2000s it was receiving $70 million per year in rebates from Purdue in exchange for preferring OxyContin on its commercial formularies.

30. In addition, Optum's affiliated research and consulting entities, OptumInsight and OptumHealth, worked hand-in-hand with Purdue and the other opioid manufacturers for decades to reshape the pain treatment market. OptumInsight provided the opioid manufacturers a full range of services including research, data, consulting, and marketing to deceive patients, prescribers, and payors into believing that opioids are effective, and even necessary, to treat chronic pain, are beneficial (both from a cost and clinical perspective), and are not likely to lead to addiction, even for patients in long term opioid therapy.

31. None of this was true and the PBM Defendants knew it. In fact, opioids are highly addictive, even in patients taking them for pain, and the risk of abuse

[5] PPLPC029000040033.

increases at higher doses and longer durations. Moreover, opioid therapy is not, in fact, particularly effective for chronic pain. Increased prescribing of opioids, for longer periods and at higher doses, and without the scrutiny that would accompany use of a drug whose risks were properly understood, would inevitably lead to increases in the number of individuals suffering from opioid use disorder ("OUD"), the clinical name encompassing the condition sometimes referred to popularly as addiction.

32. The PBM Defendants' partnership with Purdue to expand the opioid market was successful: in the years following its release, OxyContin sales exploded—growing from $48 million in 1996 to $1.6 billion by 2003—and drove a huge nationwide spike in overall opioid prescribing. During this same time, the annual number of OxyContin prescriptions for non-cancer pain increased nearly tenfold, from about 670,000 in 1997 to about 6.2 million in 2002.

33. As a direct result of the PBM Defendants' and Purdue's coordinated efforts, opioid use and abuse escalated to epidemic levels by the mid-2000s, devastating communities across the country, including Plaintiff's Community. Plaintiff has been dealing with the public health crisis caused by the PBM Defendants' misconduct for the past two decades.

34. Making matters worse, having helped launch the epidemic, the PBM Defendants then failed to close the floodgates despite knowing that opioids were causing a public health crisis. Their data told them what was happening, and they had the tools to fix it. But for years, the PBM Defendants failed to address the epidemic they helped create. Even as the federal government started requiring

certain controls be put in place in federal health plans, the PBM Defendants deliberately chose not to offer similar controls to their commercial clients with the full knowledge that such a choice would lead to continued opioid oversupply, diversion and death.

35. As the opioid epidemic spread throughout the country, including Plaintiff's community, the PBM Defendants intentionally chose not to undertake actions that they knew would have drastically reduced the inappropriate prescribing and dispensing of opioids, such as enacting effective UM protocols or disadvantaging opioids on their formularies. For example, for nearly every year for the past 20+ years, Express Scripts has preferred OxyContin on its formularies over safer, more effective, forms of pain treatment.

36. The PBM Defendants chose not to limit access to prescription opioids—including both branded and generic drugs—because together and with the opioid manufacturers, they had formed an agreement to do everything in their power to grow the market for prescription opioids without regard for public safety in order to profit from the sales of these drugs generated for each PBM Defendant and opioid manufacturer. Over at least the last two decades, the PBM Defendants have received millions of dollars in rebate payments from the opioid manufacturers in exchange for actions and omissions that incentivized and facilitated easy prescribing of prescription opioids (via favorable formulary and UM decisions), and led to unrestricted dispensing of those same drugs (through DUR decisions).

37. The PBM Defendants now publicly admit that they were "uniquely situated" to stop the opioid epidemic and that they can create UM protocols that can "ensure that physician prescribing and pharmacy dispensing is in line with the most-up-date scientific evidence and national consensus guidelines." The power that they now admit possessing is the same power that allowed them to aid and abet with the opioid manufacturers to drive the oversupply of opioids through increases in prescribing and dispensing.

38. The PBM Defendants have always had the ability to offer and the power to employ interventions that would minimize inappropriate opioid prescribing, dispensing, use, and abuse and thereby to prevent the progression of the opioid epidemic. Yet they failed to do so, not only at the outset of the opioid crisis, in the 1990's, but for two decades after that, as they watched the opioid crisis steadily unfold.

39. Despite knowing that opioids were highly addictive, overused, and heavily abused, for over two decades the PBM Defendants intentionally did little to curb inappropriate prescribing, diversion, and abuse—instead standing by while retail pharmacies (as well as their own mail order pharmacies) dispensed wildly excessive quantities of opioid prescriptions.

40. From their own data alone, the PBM Defendants could see that opioids were far more addictive and dangerous than they, along with Purdue and the other opioid manufacturers, had been telling the medical community and the public. They could see from their own data that the drugs required greater restrictions on access

than they had led their clients to believe. But the PBM Defendants had much more than just their own data to tell them that what they had been saying, and the false narrative that had been guiding their formulary and UM offerings, was untrue (even assuming they had ever believed it): in May, 2007, Purdue pleaded guilty to federal charges of criminal misbranding with respect to OxyContin. It paid a $635 million fine and entered into a Corporate Integrity Agreement that required it to ensure that its marketing of OxyContin would be fair and accurate. (Following its entry into this agreement, Purdue promptly contracted with McKinsey & Co. for advice as to how to continue to increase OxyContin sales.) As part of its plea agreement, in an agreed statement of facts, Purdue agreed that it had "with the intend to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion and less likely to cause tolerance and withdrawal than other pain medications. . . ." The agreed statement of facts detailed the ways in which Purdue's marketing had been false and misleading.

41. Thus, regardless of what they knew before Purdue entered into its plea agreement in May 2007, once that agreement was made public, the PBM Defendants had certain knowledge that the marketing activities on which they had colluded with Purdue (and with other opioid manufacturers) were fraudulent, leading to dangerous opioid oversupply and death. They also had certain knowledge that any supposed justifications for their formulary and UM offerings regarding prescription opioids—that the drugs were appropriate for prescription with minimal scrutiny, that they should be made available for a wide variety of conditions and for extended, long-term

therapy without intensive scrutiny and review—were lies. Yet it would be *ten more years* before the PBM Defendants changed their national formulary and UM offerings to place meaningful restrictions on drugs they certainly knew were too dangerous to be prescribed, dispensed, and used as freely as the PBM Defendants and Purdue had led people to believe they could be.

42. Rather than use their granular claims data to limit problematic opioid use or investigate outlier prescribing patterns, Defendants sold their data to third-party vendors who in turn resold the data to opioid manufacturers, including Purdue, who used the data to aid their marketing, so that they could continue to stoke increased prescribing of opioid drugs.

43. The PBM Defendants played an additional role in creating the opioid crisis. By virtue of operating their huge mail-order pharmacies, the PBM Defendants were often themselves the entity that dispensed the drugs (that is, filled prescriptions), a role that imposed on them affirmative duties to provide controls against diversion of these dangerous drugs. The data in their possession, both from their dispensing activities and from their prescription management activities across virtually every retailer pharmacy in the nation (over 60,000 in each of their networks), provided sufficient information and insight into patterns of prescribing to enable them to provide the controls that were required by law. They failed, however, to use this data to implement such controls. Instead, the PBM Defendants sold the data to the opioid manufacturers for them to use in their marketing efforts to *increase*

sales of prescription opioids, without regard to the effects of such increases on the potential diversion of these drugs.

44. Defendants' mail-order pharmacies have each operated within the federally-regulated closed system for controlled substances. Despite their obligations under the Controlled Substances Act to provide controls against diversion and to dispense opioids only pursuant to valid prescriptions issued for a legitimate medical purpose, they dispensed tens of billions of morphine milligram equivalents ("MMEs") (the standard measure used when measuring quantities of opioids of different strengths) of opioids into communities across the country, often without adequate due diligence to ensure that the prescriptions involved were valid and not likely to be diverted.

45. This is especially true in the case of OptumRx, which is a single entity with multiple roles. OptumRx is, and at all relevant times has been, registered with the DEA as a dispenser. DEA registrants are required to provide effective controls against diversion. But OptumRx's business practices as a PBM, as described herein, intentionally and/or negligently ignored the risks of diversion and even, at times, increased them. OptumRx's failure to implement effective controls against diversion across all of its activities that affect dispensing, whether as a mail-order pharmacy or otherwise, is a violation of its CSA duties.

46. Similarly, to OptumRx, Express Scripts, too, is registered with the DEA and as a registrant, is required to provide effective controls against diversion. It, too failed to provide the requisite controls with respect to all of its activities that affect

dispensing. It too, in its role as a PBM, intentionally and/or negligently ignored the risks of diversion and even, at times, increased them. Even though Express Scripts used separate entities to perform mail-order pharmacy and PBM functions, it, too, was required by the CSA to provide effective controls against diversion across all of its activities that affect dispensing, whether as a mail-order pharmacy or otherwise. Its failure to do so was in violation of the CSA.

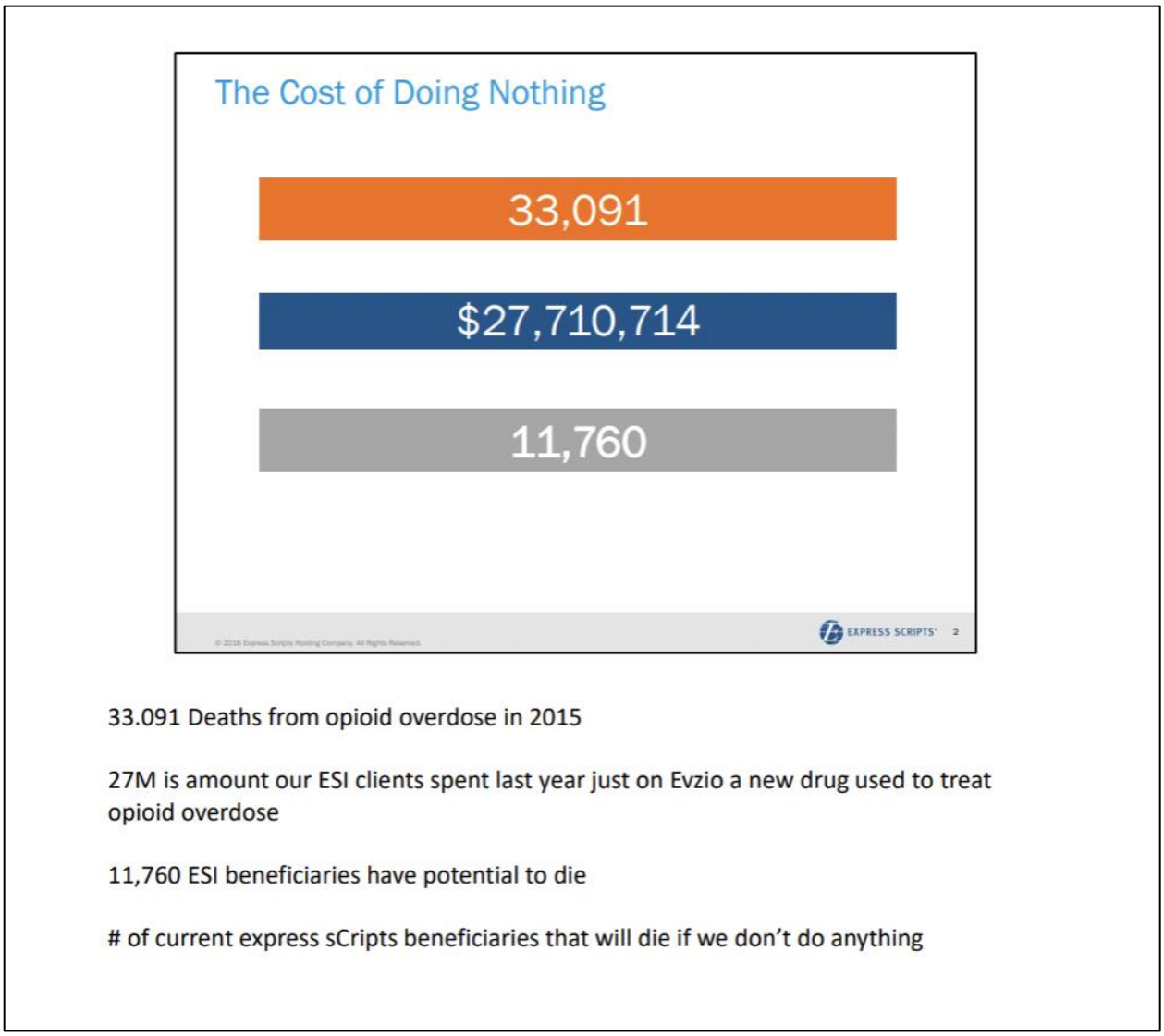
47. The PBM Defendants thus have not been mere bystanders in the opioid crisis; rather they colluded with the opioid manufacturers, placed profits over safety, and engaged in a clandestine and fraudulent scheme to increase the sale of prescription opioids, despite the known dangers of these drugs.

48. It was only well after the opioid epidemic reached its peak, and after the U.S. Senate and state governments began to investigate Express Scripts' and Optum's role in causing the opioid epidemic, that the PBM Defendants finally began to implement UM measures to address the public health crisis behind which they were a driving force.

49. Notably, when Express Scripts and Optum finally took meaningful steps to address the epidemic by enacting opioid management programs in 2017 and 2018, the results were significant. Both Express Scripts' and Optum's own data show that, following the implementation of the PBM Defendants' opioid management programs, opioid prescribing and use, as measured by multiple metrics, significantly decreased across the populations of lives that each PBM Defendant respectively covers.

50. The PBM Defendants could have implemented those same opioid management measures at any point over the past two decades. Had they put in place the tools that they knew would have reduced opioid overuse—such as those implemented in 2017—when they first knew these drugs were causing a public health crisis, they would have had a substantial impact on addressing the opioid epidemic.

51. Express Scripts' own marketing material shows with shocking precision the effect that Express Scripts' delay had on its covered lives. A March 2017 Express Scripts PowerPoint titled "Comprehensive Opioid Solution: What is Express Scripts Doing to Combat this Epidemic?" included the following slide that detailed Express Scripts' calculation of how many of its own covered lives would die in the future if Express Scripts did nothing to combat the opioid epidemic:



52. Express Scripts said nothing about the covered lives that had *already* been lost through its inaction over the decade or more that Express Scripts sat idly by and watched the opioid epidemic escalate across the country and in Plaintiff's Community. But its ability to calculate with such precision the number of such lives going forward speaks volumes both about its earlier failures to act and about the likely scale of the losses attributable to that failure.

53. Defendants' scheme has had far-reaching public health consequences, the costs of which have been borne by communities across the United States, including Plaintiff's Community.

54. According to the United States Centers for Disease Control and Prevention ("CDC"), prescription opioids have directly and indirectly accounted for more than 80% of overdose deaths in the United States, a toll that has quadrupled over the past two decades. More people have died from opioid-related causes than from car accidents or guns. More than 175 people die every day from opioid overdoses—as if an airplane were to crash, killing everyone on board, every day.

55. The epidemic's economic costs for healthcare, lost productivity, addiction treatment, and criminal justice involvement is estimated at $1.02 trillion a year.

56. The devastating human toll of opioid abuse cannot be overstated. After years of decreasing death rates in the United States, these rates are now on the rise, fueled in no small part by an increase in opioid-related drug overdose deaths. Drug overdoses are now the leading cause of death for Americans under the age of fifty. The number of Americans who died of drug overdose deaths in 2017 alone was roughly equal to the number of Americans who died in the Vietnam, Iraq, and Afghanistan wars combined.

57. From 1999 through the present, over 1,000,000 people have died from an overdose involving opioids. Well over half of those deaths involved opioids prescribed by doctors to treat pain. These opioids include brand-name prescription

medications like OxyContin, Opana ER, Nucynta, Duragesic, Subsys, Actiq, and Fentora, which were manufactured respectively by Purdue, Endo, Janssen/J&J, Insys, and Teva/Cephalon. The drugs also include generic opioids such as hydrocodone, oxycodone, fentanyl, hydromorphone, morphine, methadone, tapentadol, and oxymorphone manufactured by Teva, Mallinckrodt and other generic drug makers.

58. The opioid epidemic rages on to this day and continues to worsen each year. A staggering 110,000 people died of opioid overdoses in 2022 alone.

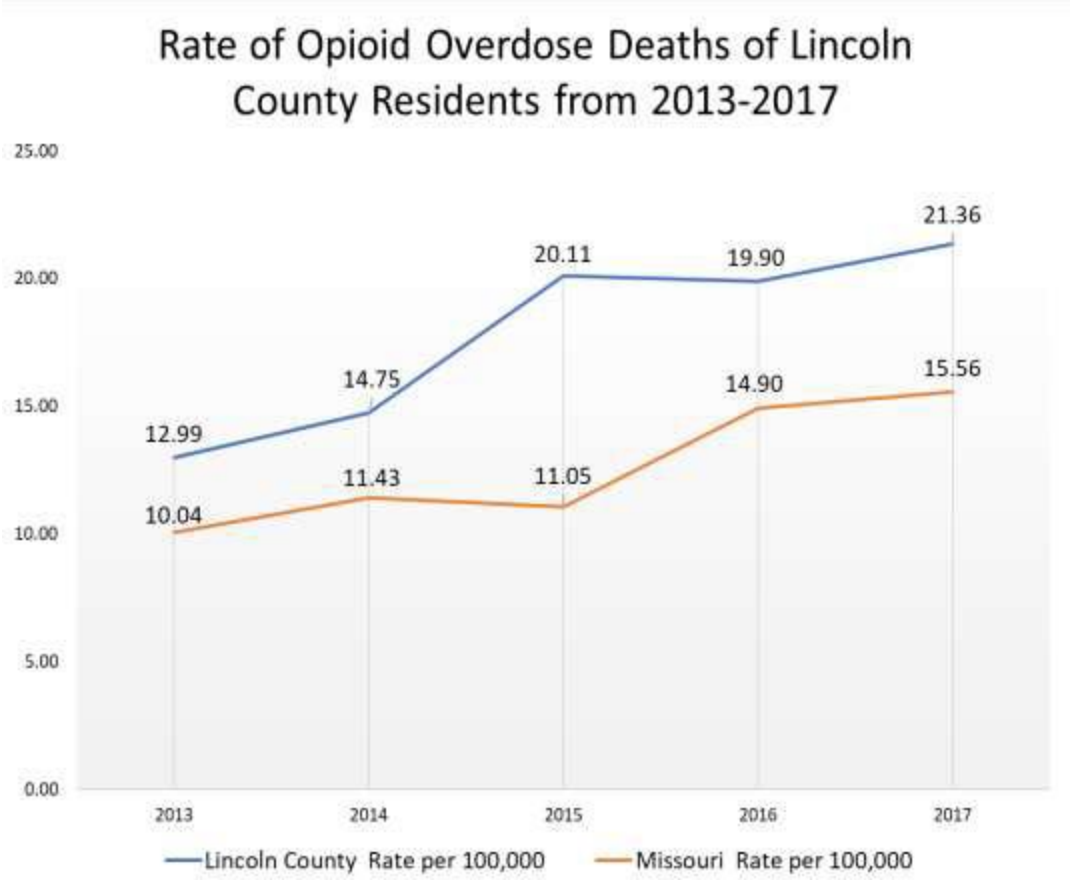
59. For many of the people whose lives were cut short by opioid overdoses, even if the drug used at the time of overdose was a non-prescription opioid such as heroin or illicit fentanyl, their opioid use began with prescription pills. Many opioid users, having become addicted to, but no longer able to obtain prescription opioids, turn to heroin. According to the American Society of Addiction Medicine, 80% of the people who initiated heroin use in the past decade started with prescription painkillers—which, at the molecular level and in their effect, closely resemble heroin. Both heroin and oxycodone, for example, are semisynthetic derivatives of naturally occurring alkaloids found in opium; heroin—or diacetylmorphine—is derived from morphine. Unsurprisingly, people who are addicted to prescription painkillers are 40 times more likely to become addicted to heroin. The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. In recent years, individuals have become addicted to even stronger opioids, often turning to illicit fentanyl, with even more lethal effects.

60. According to Robert Anderson, who oversees death statistics at the CDC: "I don't think we've ever seen anything like this. Certainly not in modern times." On October 27, 2017, then-President Trump declared the opioid epidemic a public health emergency. On December 22, 2022, Health and Human Services Secretary Xavier Becerra renewed the determination that the "opioid public health emergency exists nationwide."

61. Missouri is experiencing a drug overdose epidemic which is causing devastating socio and economic consequences. Overdose is the leading cause of death among adults 18-44 years old in Missouri. Between 1999 and 2015, Missouri experienced a 273 percent increase in the number of overdose deaths. According to the Missouri Department of Health, over 70% of drug overdose deaths involve opioids.

62. Between 2014 and 2019, an average of 1,344 Missouri residents died each year from drug overdoses. In 2020, 1,878 Missouri residents died from overdose, a 19% increase from 2019. In 2021, the number of overdose deaths rose to 2,155. However, due to incomplete reporting, these grim numbers likely understate the number of Missouri residents who have been and will be lost to this scourge.

63. As in many other communities in the United States, opioid use has been and continues to be at crisis levels in Lincoln County. Lincoln County's rate of opioid overdose deaths exceeded Missouri's rates. In 2015, Lincoln County had an opioid overdose rate of 20.11 – double the Missouri rate of 11.05. Between 2013 and 2017, Lincoln County's rate of opioid overdose deaths continued to rise and exceed Missouri's rate of opioid overdose deaths.



64. Opioids claimed 49 lives in Lincoln County from 2013-2017. The County also incurred 468 emergency room visits due to opioid use in the same time period.

65. Defendants' conduct has had severe and far-reaching consequences for public health, social services, and criminal justice, including the fueling of addiction and overdose from illicit drugs such as heroin. The costs are borne by Plaintiff and other governmental entities. These necessary and costly responses to the nationwide opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarcerations, treating opioid-dependent newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care placement, among others.

66. Government entities, including Plaintiff's Community, have been strained to the breaking point by this public health crisis, which has an impact on all of the services they provide their citizens. The burdens imposed on Plaintiff are not the normal or typical burdens of governmental programs and services. Rather, these are extraordinary costs and losses that are directly related to Defendants' conduct.

67. The losses inflicted have cut across ages and generations. Many who have succumbed to overdoses have overdosed more than once. Family members, including young children, have watched their loved ones lose consciousness or die. Young children, including toddlers, also have been the direct victims of overdoses themselves after coming into contact with opiates, often being addicted at birth from an addicted mother.

68. The resulting plague has meant that hundreds of children have been displaced from their homes and have been raised by relatives or placed in public care due to their parents' addiction. Others lose the chance to go home. Unable to be discharged from the hospital with their mothers, hundreds of babies who have been born addicted to opioids due to prenatal exposure have been placed in the care of public resources or local citizens or non-profits who do their best to comfort them through the pain of withdrawal.

69. Individually, and colluding with each other and with opioid manufacturers, Express Scripts and Optum each caused, contributed to, and maintained the opioid crisis and now must abate the ongoing public nuisance they created in communities across America.

70. Individually, and colluding with each other and with opioid manufacturers, the PBM Defendants' conduct was a substantial contributing factor in the creation of the opioid crisis, which to this day continues to unreasonably interfere with the public health, safety, and welfare and is therefore a public nuisance.

71. Express Scripts and Optum colluded together in, and aided and abetted, the fraudulent marketing of prescription opioids.

72. The PBM Defendants and opioid manufacturers formed an association-in-fact enterprise, the "Formulary & UM Enterprise." The common purpose of the Formulary & UM Enterprise was to profit from the increased and unrestricted prescribing, dispensing, and sale of prescription opioids without regard for public safety. The PBM Defendants conducted, and participated in the conduct of, the Formulary & UM Enterprise by agreeing to not take action that would undercut each other's business; agreeing to work together with the opioid manufacturers; agreeing to take and taking formulary action that would motivate and facilitate increased opioid prescribing; agreeing to take and taking UM actions that would facilitate easier and increased opioid dispensing and sales; working together with opioid manufacturers to disseminate the false marketing and to support their detailing of prescription opioids to prescribers; and failing to uphold their distribution and dispensing obligations under the Controlled Substances Act and its implementing regulations. All of this conduct furthered the underlying fraudulent scheme of the Formulary & UM Enterprise because it served to deprive people of money and

property by means of an underlying fraudulent scheme, including taking actions that directly contradicted the public representations they made about their conduct as well as the promises they made to their clients. Furthermore, Express Scripts and Optum have engaged in additional illegal conduct, including filing false statements about their revenue with the Securities and Exchange Commission ("SEC").

73. Express Scripts and Optum undertook and assumed a duty to create formularies and UM programs based on the health and safety of the public and of the lives covered by the benefit plans that were their clients. Express Scripts and Optum represented to the public, as well as to their clients, that their formulary and UM offerings were based on the health and safety of the public and the lives their clients insured, when in fact they were doing the exact opposite and the PBMs were acting to maximize their own revenue in concert with the opioid manufacturers. Optum and Express Scripts knew, at the time that they made these representations to the public and to their clients, that they would not base their formulary and UM offerings on the health and safety of the covered lives involved, nor of the public, but rather that they would make, and were already making, formulary and UM decisions, and taking formulary and UM actions, designed solely (or at least primarily) to increase profits to the PBM Defendants.

74. The opioid manufacturers—with whom the PBM Defendants colluded in creating the opioid crisis—have themselves faced substantial civil and criminal liability for their roles and have agreed to pay billions of dollars to assist with the generational devastation caused by their scheme. A few examples include:

(a) In October 2020, the Department of Justice announced that Purdue entered into a federal settlement of more than $8 billion to resolve pending criminal and civil allegations regarding Purdue's role in causing the opioid epidemic;

(b) In February 2022, Janssen/J&J agreed to finalize a proposed $5 billion settlement resolving claims by states and local governments that they helped fuel the U.S. opioid epidemic;

(c) In July 2022, Teva announced it would pay up to $4.25 billion as part of a nationwide settlement to end litigation over its alleged role in the U.S. opioid crisis; and

(d) In August 2022, Endo agreed to pay $450 million to states to resolve opioid lawsuits across the country.

75. The PBM Defendants, too, should be required to bear the costs of abating the devastating nuisance that they, along with the other entities, brought about.

76. Plaintiff brings this suit to hold Defendants accountable for the devastating opioid crisis they helped caused, contributed to, and maintained.

II. Jurisdiction and Venue

77. This Court has jurisdiction over the subject matter of this case pursuant to 28 U.S.C. § 1331 because Plaintiff's claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961, *et seq*., raise a federal question. This Court has supplemental jurisdiction over the Plaintiff's state-law claims under 28 U.S.C. § 1367 because those claims are so related to the RICO claim as to form part of the same case or controversy.

78. This Court has personal jurisdiction over the Express Scripts entities because, at all times relevant hereto, the Express Scripts entities were citizens of Missouri with their principal places of business in St. Louis, Missouri.

79. This Court also has personal jurisdiction over all Defendants because the causes of action alleged in this Complaint arise out of Defendants' transacting business in Missouri, contracting to supply services or goods in this state, causing tortious injury by an act or omission in this state, and because Defendants regularly do or solicit business or engage in a persistent course of conduct or derive substantial revenue from goods used or consumed or services rendered in this state. Defendants have purposefully directed their actions towards Missouri and/or have the requisite minimum contacts with Missouri to satisfy any statutory or constitutional requirements for personal jurisdiction. In the alternative, the Court has personal jurisdiction over all Defendants under 18 U.S.C. § 1965(b) as to Plaintiff's RICO claims and pendant personal jurisdiction over all Defendants as to Plaintiff's other claims, all of which arise out of a common nucleus of operative facts.

80. Venue is proper in this district pursuant to 28 U.S.C. § 1407.

III. Parties

A. Plaintiff

81. Plaintiff is a county organized under the laws of the State of Missouri.

82. Plaintiff provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

83. Plaintiff has all the powers possible for a county to have under the constitution of the State of Missouri and the laws of the State of Missouri.

84. Plaintiff has standing to bring this action to protect the public health, safety and welfare of its citizens.

85. Defendants' intentional, negligent, and/or unlawful conduct, alleged more fully herein, has created a serious public health crisis of opioid abuse, addiction, morbidity, and mortality and is a public nuisance in Plaintiff's Community.

86. Plaintiff directly and foreseeably sustained all economic damages alleged more fully herein. Plaintiff, like any other local government, endeavors in good faith to provide a wide variety of necessary services on a limited budget funded with taxpayer dollars. Defendants' conduct has imposed an extraordinary burden on Plaintiff's limited resources and services for which it seeks relief.

87. Defendants' conduct is beyond anything Plaintiff could have prepared for, predicted or avoided. It is a repeated course of conduct that did, does, and will—given the realities of addiction—continue to result in recurring and ongoing harm to Plaintiff. Defendants' conduct is especially pernicious when one considers the harm it has wreaked on governmental entities such as Plaintiff who, in good faith, endeavor to provide a wide variety of necessary services on a limited budget funded with taxpayer dollars. The magnitude of Defendants' scheme is neither discrete nor of a sort that a county, including Plaintiff, could reasonably expect to have to respond to at any time during its existence as such. It would be unreasonable, unjust, and inequitable not to allocate the additional governmental expenses, and any other costs associated with the harms Defendants' wrongful conduct has caused, to the actual parties responsible for creating the need for the resources to be expended as they are and were.

B. Defendants

1. The Express Scripts Defendants

88. **Defendant Evernorth Health, Inc.** (f/k/a Express Scripts Holding Company) ("Evernorth") is a Delaware corporation Evernorth Health, Inc.'s principal place of business is at 1 Express Way, St. Louis, Missouri 63121.

89. Evernorth is the parent company to all of the Express Scripts entities named as Defendants. Evernorth, through its executives and employees, controls the enterprise-wide policies that inform all of Express Scripts' lines of business in order to maximize profits across the corporate family.

90. Evernorth's conduct had a direct effect in Missouri, including Plaintiff's Community.

91. **Defendant Express Scripts, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts, Inc.'s principal place of business is at 1 Express Way, St. Louis, Missouri 63121.

92. Express Scripts, Inc. is registered to do business in Missouri and may be served through its registered agent CT Corporation System, 120 South Central Avenue, Clayton, Missouri 63105.

93. Express Scripts, Inc. holds an active license (Pharmacy Benefits Manager) with the Missouri State Department of Insurance.

94. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout Missouri that engaged in the conduct which gives rise to this Complaint.

95. During the relevant time period, Express Scripts Inc. was directly involved in the PBM and mail order services businesses, including with respect to the at-issue drugs, as well as Express Scripts' data and research services.

96. **Defendant Express Scripts Administrators, LLC,** is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts Administrators, LLC's principal place of business is at the same location as Express Scripts, Inc.

97. Express Scripts Administrators, LLC is registered to do business in Missouri and may be served through its registered agent CT Corporation System, 120 South Central Avenue, Clayton, Missouri 63105.

98. Express Scripts Administrators, LLC holds an active Third Party Administrator License with the Missouri State Department of Insurance.

99. During the relevant time period, Express Scripts Administrators, LLC provided PBM services in Missouri, including Plaintiff's Community, alleged in this complaint.

100. **Defendant Medco Health Solutions, Inc.** (f/k/a Merck-Medco) **(**"Medco") is a Delaware Corporation with its principal place of business located at 100 Parsons Pond Road, Franklin Lakes, New Jersey, and is a wholly-owned subsidiary of Evernorth Health, Inc. Medco Health Solutions, Inc. was previously known as Merck-Medco. Merck-Medco was acquired in the early 1990s by Merck & Co. as its pharmacy benefit manager subsidiary. In 2002, Merck & Co. spun off Merck-Medco into a publicly traded company, defendant Medco Health Solutions, Inc.

101. Medco Health Solutions, Inc. is registered to do business in Missouri and may be served through its registered agent: CT Corporation System, 120 South Central Avenue, Clayton, Missouri 63105.

102. **Defendant ESI Mail Order Processing, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc.

103. ESI Mail Order Processing, Inc. is registered to do business in Missouri and may be served through its registered agent: CT Corporation System, 120 South Central Avenue, Clayton, Missouri 63105.

104. During the relevant time period, ESI Mail Order Processing, Inc. provided mail order pharmacy services in Missouri, including Plaintiff's Community, alleged in this Complaint, which gives rise to the causes of action herein.

105. **Defendant ESI Mail Pharmacy Service, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. ESI Mail Pharmacy Service, Inc.'s principal place of business is at the same location as Express Scripts, Inc.

106. ESI Mail Pharmacy Service, Inc. dba Express Scripts holds six active licenses with the Missouri State Board of Pharmacy and is registered with the DEA to dispense controlled substances, including opioids.

107. During the relevant time period, ESI Mail Pharmacy Service provided mail order pharmacy services in Missouri, including Plaintiff's Community, as alleged in this Complaint, which gives rise to the causes of action herein.

108. **Defendant Express Scripts Pharmacy, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts Pharmacy, Inc.'s principal place of business is at the same location as Express Scripts, Inc.

109. Express Scripts Pharmacy, Inc. is registered to do business in Missouri and may be served through its registered agent: CT Corporation System, 120 South Central Avenue, Clayton, Missouri 63105.

110. Express Scripts Pharmacy, Inc. holds six active licenses with the Missouri State Board of Pharmacy and is registered with the DEA to dispense controlled substances, including opioids. During the relevant time period, Express Scripts Pharmacy, Inc. provided mail order pharmacy services in Missouri, including Plaintiff's Community, alleged in this Complaint, which gives rise to the causes of action herein.

111. Express Scripts Pharmacy, Inc. and ESI Mail Pharmacy Service, Inc. are referred to herein collectively as "Express Scripts Mail Order Pharmacy."

112. In 2021, Express Scripts Mail Order Pharmacy was the third largest dispensing pharmacy in the United States and reported $54.4 billion in prescription revenues.

113. From 2006 to 2014, Express Scripts Mail Order Pharmacy bought over 22.9 billion MMEs of opioids spread over 1.1 billion opioid dosage units.

114. **Defendant Express Scripts Specialty Distribution Services, Inc**. is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc.

Express Scripts Specialty Distribution Services, Inc.'s principal place of business is at the same location as Express Scripts, Inc.

115. Express Scripts Specialty Distribution Services, Inc. is registered to do business in Missouri and may be served through its registered agent: CT Corporation System, 120 South Central Avenue, Clayton, Missouri 63105.

116. Express Scripts Specialty Distribution Services, Inc. holds two active licenses with the Missouri State Board of Pharmacy and is registered with the DEA to dispense controlled substances, including opioids.

117. During the relevant time period, as alleged in more detail herein, Express Scripts Specialty Distribution Services, Inc. worked directly with the opioid manufacturers to expand the opioid market, including with Purdue and Endo to administer and dispense opioids through these opioid manufacturers' Patient Assistance Programs, including in Missouri.

118. Collectively, Defendants Evernorth Health, Inc., Express Scripts, Inc., Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Order Processing, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts Specialty Distribution Services, Inc., including all predecessor and successor entities, are referred to as "Express Scripts" or "ESI."

119. Express Scripts is named as a Defendant in its capacities as a: (1) PBM; (2) data, analytics, and research provider; and (3) mail order pharmacy. During the relevant time period, Express Scripts contracted directly with the opioid

manufacturers in each of these capacities. At all relevant times, Express Scripts performed these services in Missouri and Plaintiff's Community.

120. In 2019, Express Scripts merged with Cigna, Inc. Prior to merging with Cigna, Express Scripts was the largest independent PBM in the United States.

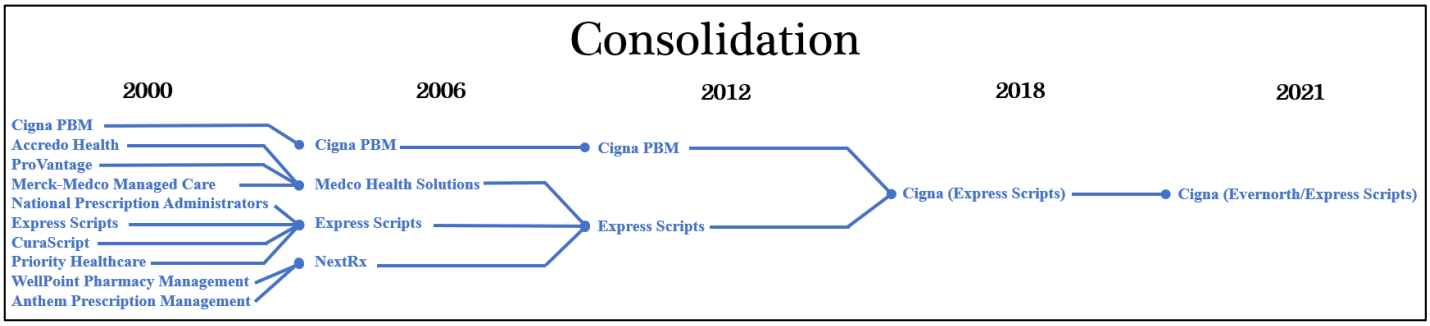
121. In 2012, Express Scripts acquired Medco in a $29.1 billion deal.

122. Prior to 2012, Express Scripts and Medco were separate companies. Standing alone, these companies were two of the largest PBMs in the country and had been since at least the mid-1990s.

123. As a result of the merger, the combined Express Scripts was formed and became the largest PBM in the nation.

124. Following the merger, all of Medco's PBM and data and research functions were combined into Express Scripts. The combined company (Medco and Express Scripts) continued under the name Express Scripts with all of Medco's clients becoming Express Scripts' clients and Medco's top executives becoming Express Scripts executives.

125. The chart represents the consolidation of PBM entities that that are now all part of Express Scripts today:



126. Express Scripts is now the largest PBM in the United States, with annual revenue (as of 2022) of over $100 billion. Express Scripts provides pharmacy benefit service to more than 100 million Americans, filling 1.4 billion prescriptions per year.

127. At all times relevant hereto, Express Scripts offered pharmacy benefit management services nationwide and maintained standard, national formularies that were offered to and used by Express Scripts' clients nationwide, including in Missouri and Plaintiff's community. Express Scripts' national formularies include its National Preferred Formulary, Basic Formulary, High Performance Formulary, and Prime Formulary. These Express Scripts formularies were utilized by prescription drug benefit plans in Plaintiff's Community throughout the relevant time period. At all times relevant hereto, those formularies dictated the terms of reimbursement for opioids dispensed in Missouri and Plaintiff's Community.

128. Express Scripts offers pharmacy benefit services to a variety of plan sponsors with covered lives in Plaintiff's Community, including both large national companies and local/regional businesses.

129. Express Scripts (and/or its predecessors) processed claims for opioids dispensed pursuant to Express Scripts' national formularies and standard UM guidelines in Plaintiff's Community throughout the opioid epidemic.

2. The Optum Defendants

130. **Defendant UnitedHealth Group, Inc**. ("UnitedHealth Group" or "UHG") is a corporation organized under the laws of Delaware with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota, 55343.

131. UnitedHealth Group may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

132. UnitedHealth Group, Inc. is a Fortune 5 diversified managed healthcare company. In 2022, UnitedHealth Group listed revenue in excess of $324 billion. UnitedHealth Group, Inc. offers a spectrum of products and services including health insurance plans and pharmacy benefits through its wholly-owned subsidiaries.

133. UnitedHealth Group operates through two connected divisions—Optum and UnitedHealthcare ("UHC"). As discussed in greater detail below, Optum provides PBM services; mail order pharmacy services; and data, analytics, consulting, and research services. UHC provides health insurance and health benefit services.

134. UnitedHealth Group, through its executives and employees, control the enterprise-wide policies that inform both UHC and Optum's lines of business in order to maximize profits across the corporate family.

135. UnitedHealth Group's conduct had a direct effect in Missouri, including Lincoln, County.

136. **Defendant Optum, Inc**. is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota.

137. Optum, Inc. is a health services company managing the subsidiaries that administer UnitedHealth Group's pharmacy benefits, including OptumRx, Inc.

138. Since 2005, Optum, Inc. has been a part of the UnitedHealth Group. UnitedHealth Group has two major segments of its business: UnitedHealth Care

("UHC") which is its medical insurance arm and Defendant Optum, Inc., which includes UHG's PBM and research, data, and consulting arms. In 2022, UHC insured over 46 million Americans and generated $249 billion in revenue.

139. Optum, Inc. is engaged in five types of business activities: (1) data analytics; (2) pharmacy benefit management; (3) healthcare services; (4) mail-order pharmacy dispensing; and (5) medical discount card services.

140. **Defendant OptumInsight, Inc.** (f/k/a Ingenix, Inc.) is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. OptumInsight was formerly known as Ingenix, Inc. The name change came after the State of New York investigated Ingenix related to a scheme to defraud consumers by manipulating reimbursement rates, resulting in a $50 million settlement with the State and giving rise to U.S. Congressional hearings.

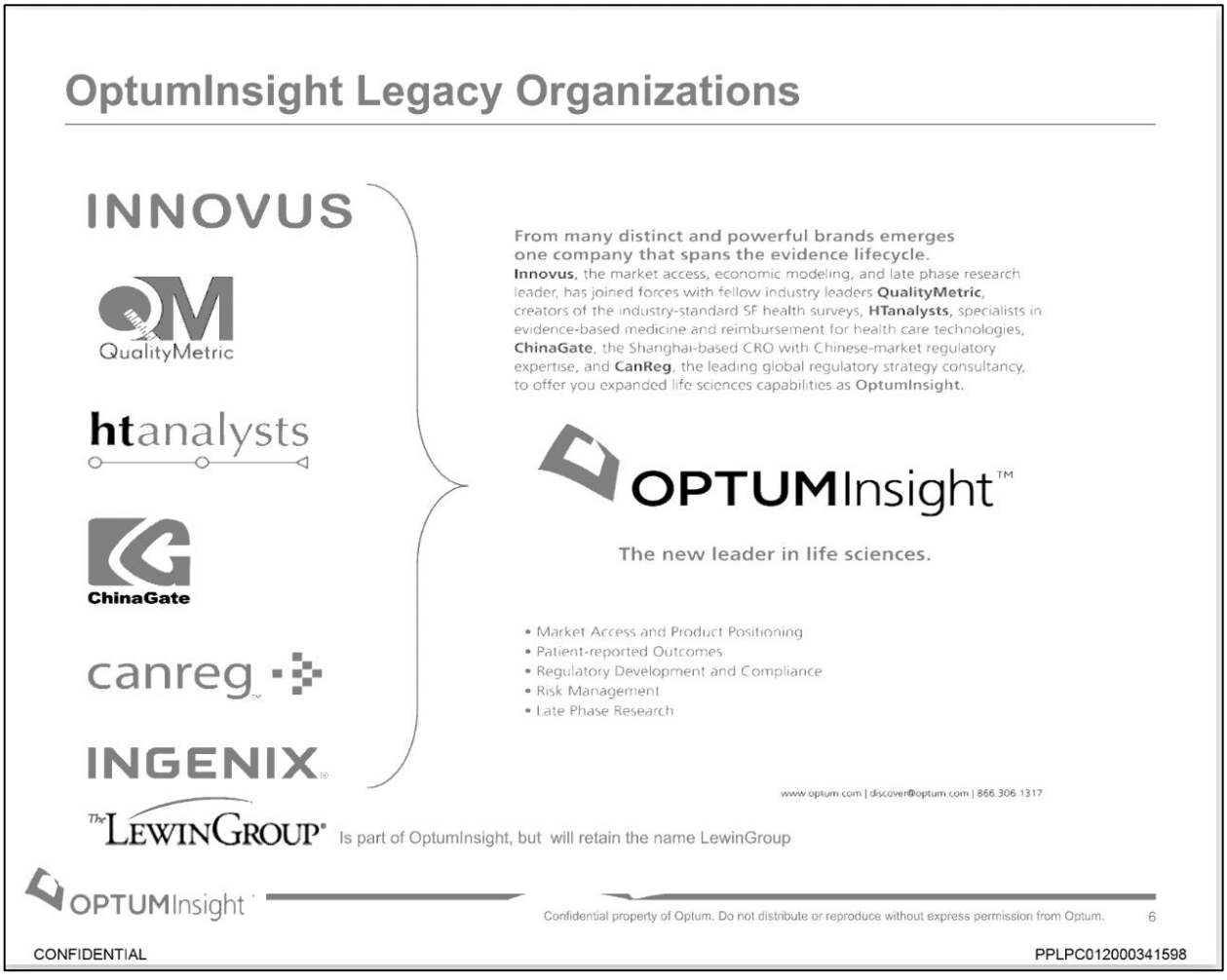
141. OptumInsight, Inc. holds an active Third Party Administrator license with the Missouri State Department of Insurance and is registered to do business in Missouri.

142. **Defendant OptumInsight Life Sciences, Inc.** (f/k/a QualityMetric, Inc.) is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. OptumInsight Life Sciences, Inc. is a wholly-owned subsidiary of UnitedHealth Group ("UHG"). Prior to 2011, OptumInsight Life Sciences, Inc. was known as QualityMetric.

143. OptumInsight, Inc., OptumInsight Life Sciences, Inc., as well as their predecessors, successors, affiliates, including but not limited to Innovus, Innovus

Research, i3, QualityMetric, HTAnalysts, ChinaGate, and CanReg, are referred to herein as "OptumInsight." OptumInsight is the Optum group that engages in data analytics.

144. OptumInsight emerged from a collection of entities acquired by the UnitedHealth Group over the years. Those legacy entities include Innovus, QualityMetric, HTAnalysts, ChinaGate, CanReg, Ingenix, and the Lewin Group.



145. As discussed more fully below, OptumInsight partnered with various opioid manufacturers to create studies, marketing, educational programs, and even

identifying algorithms to simultaneously downplaying opioids' addictive properties and expand its use and availability throughout the country, including in Missouri.

146. **Defendant OptumRx, Inc. ("OptumRx")** is a California corporation with its principal place of business at 2300 Main St., Irvine, California, 92614. OptumRx is the arm of Optum that provides PBM and pharmacy dispensing services.

147. OptumRx, Inc. is registered to do business in Missouri and may be served through is registered Agent CT Corporation System, at 120 South Central Avenue, Clayton, Missouri 63105.

148. OptumRx, Inc. holds one active Third Party Administrator license with the Missouri State Board of Pharmacy, an active Pharmacy Benefits Manager license with the Missouri State Department of Insurance, and is registered with the DEA to dispense controlled substances, including opioids.

149. Prior to 2011, OptumRx was known as Prescription Solutions. In addition, as depicted in the PBM Consolidation Chart below, OptumRx grew as a result of numerous mergers and acquisitions. For example, in 2012, a large PBM, SXC Health Solutions, bought one of its largest rivals, Catalyst Health Solutions Inc. in a roughly $4.14 billion deal. Shortly thereafter, SXC Health Solutions Corp. renamed the company Catamaran Corp. Following this, UHG bought Catamaran Corp. in a deal worth $12.8 billion and merged Catamaran with OptumRx.

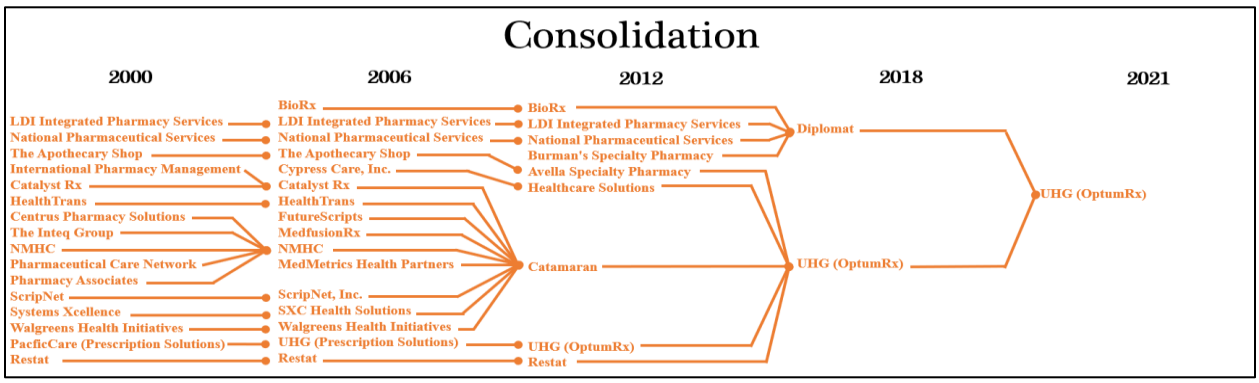
150. Prior to merging with OptumRx (or being renamed), Prescription Health Solutions, Catalyst Health Solutions, Inc., and Catamaran Corp. engaged in the at-issue PBM and mail-order activities alleged more fully herein.

151. OptumRx now provides both PBM and mail-order dispensing services. At all relevant times, OptumRx provided PBM services for entities in Plaintiff's Community.

152. At all relevant times, OptumRx has sold and continues to sell prescription opioids through its mail order pharmacies in Missouri, including in Plaintiff's Community.

153. OptumRx and all of its predecessors, including but not limited to Prescription Solutions, Catalyst Health Solutions, Inc., SXC Health Solutions Corp., and Catamaran Corp. are referred to herein as "OptumRx."

154. The consolidations that led to the emergence of OptumRx in its current form are shown on the chart below:



155. **Defendant OptumRx Discount Card Services, LLC** is a Delaware limited liability company with its principal place of business at 1423 Red Ventures Drive Building RV4, 3rd Floor, Fort Mill, South Carolina 29707.

156. OptumRx Discount Card Services, LLC is registered to do business in Missouri and may be served through its registered agent: CT Corporation System, 120 South Central Avenue, Clayton, Missouri 63105.

157. OptumRx Discount Card Services, LLC (f/k/a HealthTran, Inc., Catamaran PBM of Colorado, LLC, and Catamaran Discount Card Services, LLC) contracts with third-party businesses to administer prescription discount cards on their behalf. For example, the AARP's prescription discount card program is "endorsed" by the AARP, but is otherwise run by Optum Discount Card Services, which pays the AARP a royalty fee to the AARP for use of its intellectual property.

158. **Defendant Optum Perks, LLC** is a Delaware limited liability company with its principal place of business in Livonia, Michigan. Optum Perks, LLC is registered to do business in Missouri.

159. Optum Perks, LLC (f/k/a Script Relief, LLC) is a discount card program that originally started as a joint venture between Loeb Enterprises, LLC, and Catalyst, where by 2012 Catalyst had a 47% ownership interest. Per Catamaran's 2012 10-K, "Script Relief is a variable interest entity with Catamaran being the primary beneficiary, as the Company's underlying PBM and pharmacy contracts represent Script Relief's key business operations and the Company has the power to direct these activities."

160. By 2019, OptumRx, Inc. had fully acquired Script Relief and renamed the program Optum Perks.

161. **Defendant OptumHealth Care Solutions, LLC** is a Delaware limited liability company with its principal place of business at 11000 Optum Cir., Eden Prairie, Minnesota 55344.

162. OptumHealth Care Solutions, LLC is registered to do business in Missouri and may be served through its registered agent: CT Corporation System, 120 South Central Avenue, Clayton, Missouri 63105.

163. OptumHealth Care Solutions, LLC holds an active Third Party Administrator license with the Missouri State Department of Insurance.

164. OptumHealth for a number of years partnered with Purdue to educate many case managers, nurse practitioners, and medical directors throughout UnitedHealth Group's various enterprises. These programs were specifically endorsed and coordinated through one of Optum Health's national medical directors. The content of these programs targeted pain as an undertreated disease, among other issues, and contained the similar dangerous messaging regarding the use of OxyContin that Purdue plead guilty to in 2007.

165. **Defendant OptumHealth Holdings, LLC** is a Delaware limited liability company with its principal place of business at 11000 Optum Cir., Eden Prairie, Minnesota 55344.

166. **Defendant Optum Health Networks, Inc.** is a Delaware corporation with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota 55343.

167. Optum Health Networks, Inc. is registered to do business in Missouri and may be served through its registered agent: CT Corporation System, 120 South Central Avenue, Clayton, Missouri 63105.

168. Optum Health Networks, Inc. is registered as a Third Party Administrator with the State of Missouri Department of Insurance.

169. Optum Health Networks, Inc. provides care services to enrolled members of its subsidiaries and parents that includes care management services, arranging for delivery of services, and managing client relationships and contracts for access to said services.

170. Together, OptumHealth Care Solutions, LLC, Optum Health Holdings, LLC, and OptumHealth Networks, Inc. are referred to herein as "OptumHealth."

171. OptumHealth is a healthcare service provider that includes specialty health services, health banking services, ancillary care networks, and health education and information services to both individuals and health care professionals. It does this through four main lines of business: Care Solutions, Behavioral Solutions, Specialty Benefits, and Financial Services. In 2022, OptumHealth served 102 million individuals.

172. Relevant to the opioid epidemic and Plaintiff's claims—detailed *infra*—OptumHealth partnered with Purdue throughout the 2000s to provide "education" to health care providers, including medical directors, nurse practitioners, case managers, and care advisors throughout the country, and in Missouri, regarding the so-called "undertreatment" of pain and expanding the use of opioids.

173. Collectively, OptumRx, Optum, Inc., Optum Discount Card Services, LLC, Optum Perks, LLC, OptumHealth Care Services, LLC, OptumHealth Holdings,

LLC, Optum Health Networks, Inc., and OptumInsight are referred to herein as "Optum."

174. Optum is named as a Defendant in its capacities as a: (1) PBM; (2) data, analytics, consulting, and research provider; and (3) mail-order pharmacy. During the relevant time period, Optum contracted directly with opioid manufacturers in each of these capacities. At all relevant times, Optum performed these services and derived substantial revenue in Missouri, including in Plaintiff's Community.

175. Optum, Inc. is a health services company comprising three sectors—OptumRx, which manages pharmacy benefits for both UHC and third party clients; OptumHealth, which provides medical services as well as education and support for individuals throughout the country; and OptumInsight, which is the data, research, and consulting sector.

176. OptumRx is the third largest PBM in the United States. It provides PBM services to more than 65 million people.

177. At all times relevant hereto, OptumRx offered pharmacy benefit management services nationwide and maintained standard, national formularies that were offered to and used by OptumRx's clients both across the country and in Plaintiff's Community. At all times relevant hereto, those formularies included opioids, including those at issue in this case. OptumRx national formularies include the Essential Health Benefits, Generic Centric, Core Standard, Core Choice, Select Standard, Select Choice, Premium Standard, and Premium Choice.

178. Optum (and/or its predecessors) processed claims for opioids dispensed pursuant to Optum's standard, national formularies and utilization management guidelines in Plaintiff's Community throughout the opioid epidemic.

179. In addition to its pharmacy benefit services, Optum entities also provide services related to pharmaceutical reimbursement and dispensing that generate revenue and benefit from a lack of opioid controls.

180. At all times relevant hereto, Optum offered mail-order pharmacy services and dispensed opioids in Missouri, including Plaintiff's Community.

181. In 2021, Optum's mail order pharmacy was the fourth largest dispensing pharmacy in the United States and received $34.2 billion in prescription revenues.

182. From 2006 to 2014, Optum's mail order pharmacy bought over 4.5 billion MMEs of opioids spread over 252 million opioid dosage units.

183. OptumInsight, Optum's data, research, and consulting arm, is one of the largest health information, technology, and consulting companies in the world. It collects, processes, sells and profits from the vast data all managed lives—which in 2011 covered over 75 million lives. It also provides clinical research, consulting, marketing advisory services, and analytics tools to its clients.

184. OptumInsight is an integral part of the conduct that gives rise to Plaintiff's causes of action. As alleged in detail herein, throughout the relevant time period, OptumInsight worked directly with opioid manufacturers to convince

patients, prescribers, payors and the public that long term opioid use was appropriate for the treatment of chronic pain and that opioids were not addictive.

185. Each opioid manufacturer had dedicated executives assigned to work with OptumInsight. The opioid manufacturers used their relationships with OptumInsight to deepen their ties to the overall Optum corporate family.

186. OptumInsight was paid tens of millions of dollars by the opioid manufacturers during the relevant time period for its work to expand the opioid market.

IV. The Role of PBMs in Prescription Drug Transactions

A. PBMs Operate on All Sides of Prescription Drug Transactions

187. PBMs such as Express Scripts and OptumRx contract with insurers, self-insured employers, and state and federal government agencies (referred to by the PBMs as their "clients") to provide pharmacy benefit management services. One of the services the PBMs provide is to create standard, national formularies and UM programs. The PBMs offer these standard formularies and UM programs to their clients, and most clients adopt these standard offerings for their prescription drug plans without modification. In crafting these standard formularies and UM programs, PBMs review and make determinations regarding which medications are effective or appropriate. PBMs also review and pay claims for the drugs dispensed to their covered lives. As a result, PBMs exert significant influence over prescriptions dispensed in the United States and in Missouri, including influencing the quantity, dosage strength, duration, and refill availability for each prescription. PBMs also collect and maintain all of the data associated with all of the prescriptions dispensed

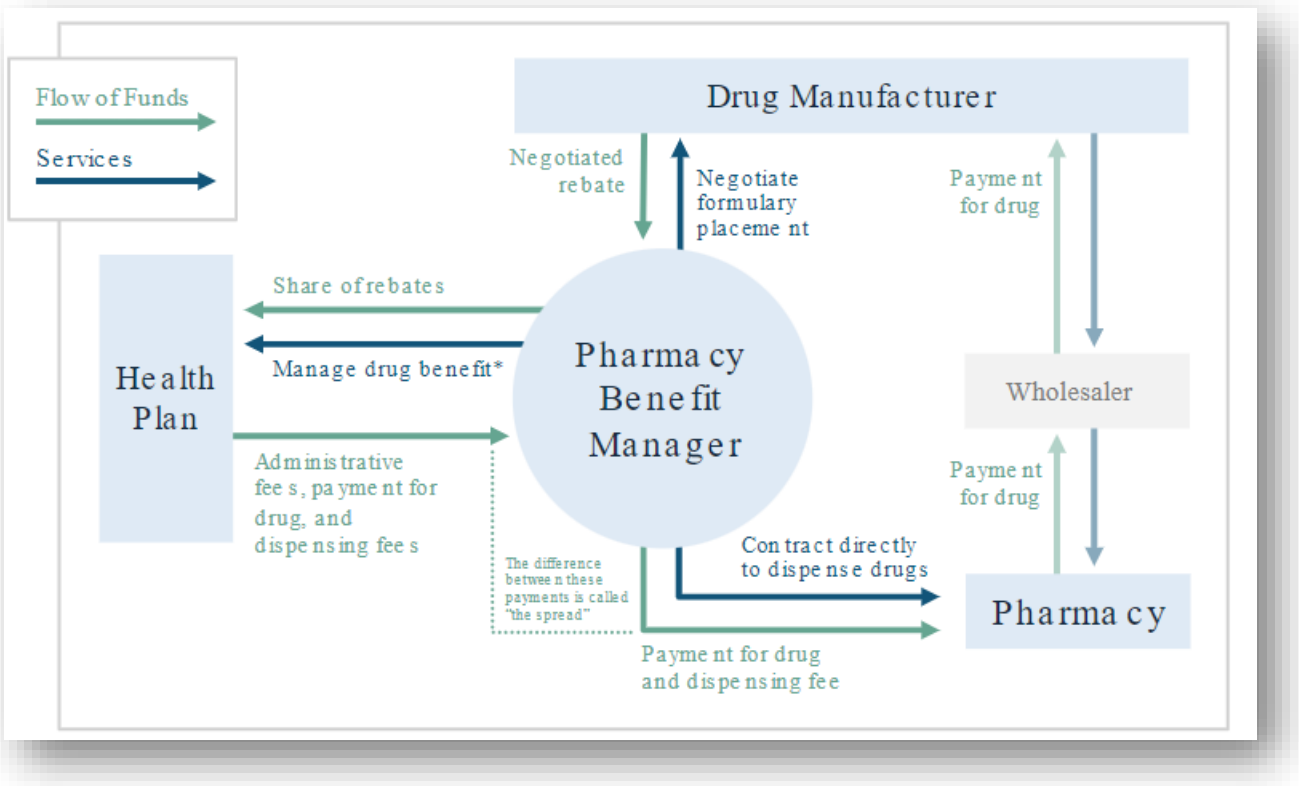
to their covered lives, giving them granular insight into the ongoing health and pharmaceutical patterns of these patients. This data is available to the PBMs when they craft their standard formularies, implement standard UM programs and even informs standard "retrospective utilization" programs that offer services to patients after a prescription has been filled.

188. Although PBMs contract with third-party payors to provide pharmacy benefit management services, they also contract with drug manufacturers and with pharmacies. They are paid by their clients to make safe and effective drug therapies available to their covered lives. But, as described below, they are also paid by drug manufacturers to provide the greatest access to their products, so as to increase sales, with little to no regard for safety or efficacy. And they are paid by the pharmacies where the plan beneficiaries' prescriptions are filled, to verify coverage but also to assist the pharmacy in ensuring that a prescription is appropriate. Thus, in any given transaction, a PBM may be receiving money from both the payor and the pharmacy to exercise independent judgment about whether to authorize payment for a prescription, while also receiving money from the manufacturer to ensure that the sale is made.

189. The business model that PBMs, including the PBM Defendants, use is thus rife with conflicts of interest and self-dealing through which they have enriched themselves at the expense of their clients and the public. Inherent in the services offered by the PBM Defendants in their agreements with the opioid manufacturers (and with pharmacies) are the same services for which they are already ostensibly

receiving payment from their clients, albeit with the incentives often running in the opposite direction.

190. This chart illustrates the central role the PBM Defendants play in the prescription drug market:[6]



191. It is in part because of the multiple roles that PBMs play in prescription drug transactions that they have access to, and collect, the vast amounts of data they have. No other party has access to so much data because no other party is so

[6] The Commonwealth Fund, *Pharmacy Benefit Managers and Their Role in Drug Spending* (Apr. 22, 2019), https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending.

thoroughly embedded into every aspect of prescription drug prescribing and dispensing.

192. Yet rather than use their vast data resources to craft formulary and UM offerings that would address the dangers of opioids and help reduce utilization of these dangerous drugs, the PBM Defendants instead worked with opioid manufacturers to adopt policies and offerings that drove opioid utilization and helped fuel the epidemic. In pursuit of opioid profits, the PBM Defendants intentionally disregarded their obligations, to the detriment of communities around the country, including Plaintiff's Community.

B. PBMs Use Their Formularies as Leverage to Negotiate with Drug Manufacturers

193. Formularies are a central tool that PBMs, including the PBM Defendants, offer to clients for use in designing, managing and publicly identifying the extent of the coverage and benefits provided to their covered lives. Because formulary listing affects how much a patient pays for a drug, formulary placement makes a prescriber more likely to prescribe, and a patient more likely to pay for, certain drugs over others. Indeed, driving drug utilization is one of the key purposes and functions of formulary design, implementation, and management.

194. Moreover, the PBMs' clients rely upon the PBM Defendants' formularies. The Pharmaceutical Care Management Association ("PCMA"), the PBM trade association, testified to the Pennsylvania House of Representatives that even sophisticated clients rely almost entirely on PBMs to manage their drug benefit. Indeed, it is their expertise that the PBMs are marketing to their clients, so it makes

sense that most clients rely on that expertise and, lacking their own expertise, have little choice but to do so. Many PBM clients utilize the PBMs' standard national formularies. Even though there may be a few large, sophisticated clients that ostensibly use "custom" formularies, in reality, these formularies often either mirror the PBMs' standard formularies or were constructed in large part by the PBMs.

195. Since the PBM Defendants' standard formulary offerings heavily influence drug reimbursement terms for 160+ million covered lives, the PBMs have significant leverage when negotiating with brand drug manufacturers. The PBM Defendants use this leverage to maximize the amount of rebates paid to them by brand drug manufacturers, including opioid manufacturers. These rebates are paid to the PBMs on every eligible drug dispensed; thus, the more the PBMs drive utilization, the more rebates are paid by opioid manufacturers to the PBMs.

196. Rebate eligibility is a critical factor. In a typical PBM rebate contract with an opioid manufacturer, eligibility for rebate payments is tied to the way a particular drug is treated on the formulary and whether the drug is or is not "restricted" by UM. Put differently, if a drug is placed on a non-preferred tier, or if the drug is restricted by UM programs, rebates will either be adversely impacted or not paid at all.

197. Thus, the PBM Defendants are incentivized to structure their standard formulary and UM offerings in ways that enhance and do not restrict opioid utilization so that they can maximize the rebate payments for which they will be eligible.

198. PBMs do at times share manufacturer rebates with their clients. But the PBM Defendants generally pass through only a portion of these rebates to their clients and retain the rest as profit. As a result, the PBM Defendants have profited handsomely from rebates received from drug makers, including opioid manufacturers, for each brand drug sold.

199. In addition, if a PBM can generate higher volume (more sales) for manufacturers, it can then negotiate higher rebates that the manufacturer will pay to the PBM (which in turn increases the PBMs' profit).

200. PBMs also make money other ways by increasing the volume of prescriptions that are sold to their covered lives. One way is through money that the PBMs earn on "spread pricing." Spread pricing is where a PBM will charge its client a higher price for a prescription than what the PBM pays the pharmacy for the same drug. The PBM will then pocket the difference in this price spread as profit. Spread pricing is particularly profitable for the PBMs for generic drugs, including generic opioids. Put simply, the more generic opioid prescriptions dispensed to the PBMs' covered lives, the higher profit the PBM earns through this spread pricing.

201. Ultimately, PBMs are very much incentivized to keep sales volumes high for both generic and brand opioids.

202. As a result, PBMs—including Defendants here—have a monetary interest in ensuring that favored drugs are covered, prescribed, and dispensed.

203. The structure of the pharmacy benefit market also aids the PBM Defendants' efforts to maximize opioid manufacturer rebates. PBM Defendants

became a major force in the late 1980s, expanding from solely processing pharmacy claims to a business model that invited drug manufacturers to negotiate prices in several drug categories. Because of market consolidation, the PBM Defendants control a significant portion of the pharmacy benefit market. The PBM market is thus highly concentrated, both within Missouri and throughout the United States.

204. In contrast, the market for their clients is much less concentrated, with the largest companies accounting for less than two-thirds of the business in 2014. For brand-name drug manufacturers, thirteen companies account for 90% of the U.S. pharmaceutical market. Thus, it is typical to have one of the (large) PBMs negotiating with the (large) opioid manufacturers on behalf of a number of relatively small clients.

205. The small world consisting of the PBM Defendants and approximately ten opioid manufacturers facilitated collusive negotiations that benefitted the manufacturers and the PBM Defendants at the expense of patient health and safety. For example, PBMs have typically used their clout to negotiate master rebate agreements on behalf of all their covered lives. Rather than negotiate with respect to, or on behalf of, particular clients or particular plans, they enter into master agreements that will apply across the board. As a result, in the world of drug price negotiation, market power is most highly concentrated among the PBM Defendants, who have more negotiating leverage than any individual drug manufacturer or health plan on either side of a transaction.

206. These negotiations can be of such great financial importance to pharmaceutical companies and the PBM Defendants that they are often attended by senior executives up to and including the chief executives, which has also facilitated the formation of personal business relationships and an understanding of the common purpose of the negotiations between the PBM Defendants and the opioid manufacturers.

207. Because the PBM Defendants are paid based on the volume of prescriptions, including for opioids, that flow through their formularies, restricting this flow would cause the PBM Defendants to lose substantial revenue.

208. Moreover, rebate payments are only part of the payments PBM Defendants receive from opioid manufacturers. In addition to rebates, drug manufacturers, including opioid manufacturers, have paid the PBM Defendants substantial amounts of various "administrative fees" and "service fees" in exchange for, among other things, ensuring a given drug's formulary placement and providing various services to the drug makers—the same services they are already being paid to provide to their clients.

209. For example, Express Scripts' standard form of contract discloses that it receives "administrative fees" for, among other things, providing opioid manufacturers access to "drug utilization data, and receives "service fees" (which are explicitly described as separate from both rebates and administrative fees) for "formulary compliance initiatives, clinical services, therapy managements services, education services, medical benefit management services, including, for example,

formulary compliance initiatives, clinical services, therapy management services, education services, medical benefit management services, and the sale of non-patient identifiable claim information":

> ESI provides administrative services to formulary rebate contracted manufacturers, which include, for example, maintenance and operation of the systems and other infrastructure necessary for managing and administering the PBM formulary rebate process and access to drug utilization data, as allowed by law, for purposes of verifying and evaluating the rebate payments and for other purposes related to the manufacturer's products. ESI receives administrative fees from the participating manufacturers for these services. These administrative fees are calculated based on the price of the rebated drug or supplies along with the volume of utilization and do not exceed the greater of (i) 4.58% of the average wholesale price, or (ii) 5.5% of the wholesale acquisition cost of the products. In its capacity as a PBM company, ESI also may receive service fees from manufacturers as compensation for the performance of various services, including, for example, formulary compliance initiatives, clinical services, therapy management services, education services, medical benefit management services, and the sale of non-patient identifiable claim information. These service fees are not part of the formulary rebates or associated administrative fees.[7]

210. The PBM Defendants are able to minimize the portion of monies from drug manufacturers that they pass along to their clients in part through misleading labeling of the various payments. This lack of transparency, and the PBM Defendants' central role in ensuring it, has allowed the PBM Defendants to conceal their collusion with the opioid manufacturers from their own clients and from the public.

211. As industry expert Linda Cahn observed, "[i]f a PBM enters into contracts with drug manufacturers and chooses to give rebates another name—like

[7] ESI_JEFFCOMO_000231588 (1/1/14).

administrative fees or health management fees or grants—the PBM will arguably eliminate its obligation to pass through the financial benefits to its clients."[8]

212. Administrative fees can make up a substantial portion of the total dollar amount of drug company payments to a PBM. According to pharmacy-benefits consultant David Dross, administrative fees can amount to 25-30% of total payments from drug companies like Purdue.

1. Express Scripts' Formularies

213. Express Scripts develops its operative national formularies utilizing three committees—Therapeutic Assessment Committee ("TAC"), Pharmacy & Therapeutics Committee ("P&T"), and the Value Assessment Committee ("VAC"). The TAC reviews the clinical properties of new drugs and pre-existing drugs (to the extent new or developing clinical information warranted such review) and prepares research memoranda discussing the benefits and drawbacks for each drug. The TAC also makes recommendations regarding whether any particular drug under review should or should not be included on Express Scripts' national formularies. The TAC's research memoranda and recommendations are then provided to the Express Scripts' P&T Committee.

214. The P&T Committee consists of outside, third-party medical providers who were not employees of Express Scripts. Express Scripts claims that the P&T is

[8] Jeanne Pinder, "Don't Get Trapped By PBM's Rebate Labeling Games: Managed Care magazine by Linda Cahn" *Clear Health Costs* (Feb. 26, 2018), https://clearhealthcosts.com/blog/2018/02/dont-get-trapped-pbms-rebate-labeling-games-managed-care-magazine/.

fully independent and exercises its own clinical judgment. Express Scripts further claims that "the P&T Committee considers the drug's *safety and efficacy*," and the company "fully compl[ies] with the P&T Committee's clinical recommendations regarding drugs that must be included or excluded from the formulary based on their assessment of *safety and efficacy*."[9]

215. The P&T reviews the research memoranda provided by TAC. The P&T then places each drug it reviewed into one of three categories: "must include," which meant that the drug must be included on Express Scripts' national formularies; "must exclude," which meant the drug could *not* be included on Express Scripts' national formularies; and "optional," which meant that the drug could or could not be included on national formularies, at the discretion of yet a third committee.

216. This third committee is known as the VAC. Like the TAC, the VAC also consists of Express Scripts employees. But, in important other respects, the VAC is different. Notably, while Express Scripts represents that neither the TAC nor the P&T is supposed to consider any financial or economic factors, the VAC expressly considers financial factors. The financial factors considered by the VAC include rebates and administrative fees paid by manufacturers, including the opioid manufacturers. At all times Express Scripts has benefited from these rebates and administrative fees, because Express Scripts retains some portion of them. After giving consideration to these financial factors, the VAC is then the committee that

[9] *Id.* (emphasis added).

actually constructs the Express Scripts' national formularies, and determines on which tier a drug is placed. The lower the tier, the greater the access/utilization.

2. Optum's Formularies

217. OptumRx develops its formularies through a process primarily involving the following committees: the Clinical Programs Subcommittee ("CPS"); Drug Intelligence; the National Pharmacy and Therapeutics Committee ("P&T"); and the Business Implementation Committee ("BIC").

218. The CPS is an advisory subcommittee of the P&T. CPS's role is to: (1) review and approve treatment guidelines for patients with specific conditions; (2) review and approve clinical algorithms for disease state management and other clinical activities; (3) review and approve prior authorization algorithms and decision support tools; (4) provide expert guidance to the P&T regarding national and local guidelines for medical care; (5) review certain UM for medications and make recommendations to the BIC committee based on those reviews.

219. OptumRx's P&T committee's role is to: (1) review PBM formularies and PDLs at least annually for drug inclusions/exclusions; (2) review and approve clinical guidelines and/or criteria and procedures related to the timely use of and access to medications annually; (3) create procedures that guide UM tools and formulary management activities; and (4) advise on clinical education programs for plan sponsors' members, health care provider networks, plan participants, and pharmacy providers.

220. OptumRx's P&T committee creates recommendations on formulary inclusion, UM, and clinical programs that are then provided to the BIC. The BIC

determines the tiering and UM for the OptumRx national formularies. The BIC's recommendations are informed by "financial analysis." When determining clinical program, or UM strategies, the BIC also considers economic and pharmacoeconomic evidence.

221. Once the BIC has made its final recommendations regarding formulary placement and utilization management for medications, it communicates those to OptumRx. The final formularies are then provided to the client.

C. PBMs Drug UM Programs

222. In connection with their formulary development, PBMs, including the PBM Defendants, also create standard drug UM programs and rules, which they offer to their clients and which most clients adopt.

223. One example of UM offered by the PBM Defendants since at least the late 1990s is a "quantity limit," or QL, which is a utilization management tool that limits the total dosage of a particular drug that a beneficiary may receive. Another example is a "step edit" or "step therapy," which requires a patient to try a different drug (designated by the PBM) before the patient can receive the drug they were prescribed. Another is a "prior authorization," or PA, which is a tool that requires a clinical follow-up with the prescribing physician prior to the drug being dispensed to double-check and make sure the prescription is appropriate for the patient beneficiary.

224. Studies, including those conducted by the PBM Defendants themselves, have shown that implementing PAs can reduce the utilization of dangerous and addictive drugs like OxyContin. Thus, like their standard formulary offerings,

standard UM offerings are another tool the PBM Defendants use to steer patients. UM tools, if used as intended, should act as an impediment to patients gaining access to drugs that are susceptible to oversupply and abuse, or that are more costly than others.

225. Express Scripts and OptumRx's business is set up on a model of standardization. While clients have the option to design their own programs, most clients accept the PBM Defendants' standard formularies and UM programs, like step therapy, prior authorizations and drug utilization review ("DUR") edits. Thus, it is the manner in which Express Scripts and OptumRx construct their standard formularies and programs (outside of any client interaction) that has an enormous influence on drug utilization.

226. The amount of influence that each PBM Defendant had over drug utilization was a frequent topic of discussion between the PBM Defendants and the opioid manufacturers that was central in the parties' discussions about rebates and administrative fees. The more a PBM Defendant could drive market share to or away from a drug by controlling formulary and UM decisions, the more an opioid manufacturer was willing to pay.

227. Notably, the PBM Defendants leverage their ability to steer drug utilization to generate substantial profits. Indeed, Express Scripts and Optum profit from every branded and generic opioid sold in myriad ways.

228. Express Scripts and OptumRx have always had the ability to provide baseline opioid UM controls for its clients, which they did on September 1, 2017 (when

Express Scripts offered its Advanced Opioid Management program) and January 1, 2018 (when it kicked off its Opioid Risk Management Program).

D. PBMs Contract with Pharmacies

229. As noted above, PBMs, including the PBM Defendants, also contract directly with retail pharmacies to dispense drugs to a patient.

230. Express Scripts contracts with approximately 65,000 retail pharmacies, representing over 98% of all retail pharmacies in the United States. These pharmacies become part of Express Scripts' network for coverage purposes.

231. Similarly, Optum contracts with a network of more than 70,000 retail pharmacies and multiple delivery facilities.

232. When a pharmacy is in the network with Express Scripts and Optum (and generally with both), a covered life pays out-of-pocket for a small portion of the prescription and the PBM arranges for direct payment to the pharmacy of the remainder of the cost of the prescription. In this way, covered lives need not advance the cost of their prescriptions and seek reimbursement afterwards.

233. In connection with contractual arrangements with their network pharmacies, the PBM determines the patient's copay and how much it will reimburse pharmacies for each medication covered under the drug plan. PBMs generally pre-determine how much each drug covered under their standard formularies should cost, and this determination affects the amount they reimburse to the pharmacies. Critically, the PBM Defendants also receive real-time claims data from pharmacies at the point of sale, as part of their electronic adjudication of claims, which includes

determining eligibility for reimbursement and conducting concurrent drug utilization review ("cDUR," discussed in detail below).

234. As described below, pursuant to its contracts with its network of pharmacies, Express Scripts undertakes to perform "drug utilization review" and to provide mechanisms to ensure safe dispensing. Express Scripts claims that it uses drug utilization review to "review prescriptions for safety and effectiveness, in real-time, electronically and systematically, when presented to our pharmacies or submitted for coverage by network pharmacies, and alert the dispensing pharmacy to detected issues. Issues not adequately addressed at the time of dispensing may also be communicated to the prescriber retrospectively."[10]

235. Through its contracts with its network pharmacies, Optum similarly undertakes to perform services, including drug utilization review, to ensure safe dispensing.

V. The PBM Defendants' Role in Causing the Opioid Crisis

A. The PBM Defendants and the Opioid Manufacturers Colluded to Ensure Virtually Unfettered Access to Opioids

1. The PBM Defendants Negotiated with the Opioid Manufacturers to Give Opioids Favorable Placement on National Formularies in Exchange for Rebates and Other Fees

236. As noted above, PBMs have significantly more market power than the drug manufacturers with whom they negotiate drugs prices and formulary placement. The vast market power of the PBM Defendants compared to their clients

[10] *Id.*

has allowed the PBM Defendants to negotiate deals with the opioid manufacturers for the payment of additional rebates and other fees that the opioid manufacturers pay to the PBMs that induced the cooperation of the PBM Defendants and the opioid manufacturers to work together in a fraudulent scheme.

237. The terms of the agreements between opioid manufacturers and the PBM Defendants are considered extremely confidential by the PBM Defendants and are not even disclosed to their health plan clients. As a result, until key highly confidential documents were recently obtained in discovery in *In re: National Prescription Opiate Litigation*, Case No. 1:17-md-2804-DAP (N.D. Ohio), and other opioids litigation, there has been little public insight into how these agreements affected the volume of opioids flooding American households.

238. From the time it first released OxyContin, Purdue pushed its sales force to "*Sell, Sell, Sell* OxyContin."[11] In an early sales memo in 1996, Purdue's head of sales stressed that his team should "[r]emain focused on positioning OxyContin as the opioid to start with and stay with in chronic malignant and non-malignant pain states. In addition, continue to aggressively position OxyContin for use in osteoarthritis, low back pain, post neuropathic neuralgia and post-surgical applications."[12]

239. Purdue's aggressive marketing campaign worked and OxyContin sales exploded in the years following its release, reaching almost $2 billion in annual sales

[11] PDD1503490547.

[12] *Id.*

by 2003. In addition, during this same time period the annual number of OxyContin prescriptions for noncancer pain increased nearly tenfold, from about 670,000 in 1997 to about 6.2 million in 2002.

240. During this time of rapidly expanding OxyContin sales, Medco was the largest customer of Purdue products. For example, in 1996, Medco was the largest PBM in the country and received over one-third of the rebates paid by Purdue for all opioid sales. By 2001 and 2002, Medco's gross sales of Purdue opioids totaled $250.4 million and $281 million respectively, "making [Medco Purdue's] largest customer."[13]

241. When OxyContin was first released, Medco made several attempts to restrict its utilization. For example, in early 1996, Medco established a "ceiling dose" quantity limit for OxyContin of 80 mgs/day because of the potential for abuse for that drug.[14]

242. In January 1997, Purdue received notice from "pain clinic doctors" that Medco was sending letters to prescribers because of a "concern[] about abuse potential" in patients taking OxyContin for chronic non-malignant pain.[15] Medco's concerns were forwarded up to several high ranking Purdue executives, including the president of the company, Richard Sackler.[16] James Lang, head of marketing and sales at Purdue, explained, "Our success with OxyContin is starting to create concerns amongst the large PBMs as you already know because they recognize we

[13] PPLPC012000064369.

[14] PDD1715057333.

[15] E513_00045035.

[16] E513_00006452; E513_00045035; PDD9316506319.

are targeting non cancer pain. This goes beyond their initial perception that [OxyContin] was primarily a cancer pain medication."[17]

243. While this issue was originally presented as a concern about addiction and abuse, a number of Purdue executives saw this as pretextual, and thought that Medco's true intentions were focused on cost and extracting larger rebates.

244. For example, when Purdue's medical director Paul Goldenheim suggested, "[w]e need to talk to Medco and others about addiction," Purdue's president Richard Sackler responded, "we should consider that 'addiction' may be a convenient way to 'just say 'NO' and when this objection is obliterated, [Medco] will fall back on the question of cost."[18]

245. Mark Alfonso, Purdue's vice-president of marketing, also weighed in: "My impression of this issues is that there are several major products . . . that are growing at a great rate and [managed health care][19] organizations are not slowing them. . . I also believe that a lot of what [Purdue's Managed Care Account Executives] hear from their accounts is with the intention of softening them up before the [managed health care] asks for more aggressive rebates. They are told 'I am going to drop you from the formulary' for several months and then one day they are told if you give me higher rebate you can keep OxyContin in the formulary."[20]

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[17] *Id.*

[18] *Id.*

[19] Purdue refers to payors, such as the PBM Defendants, as "managed care."

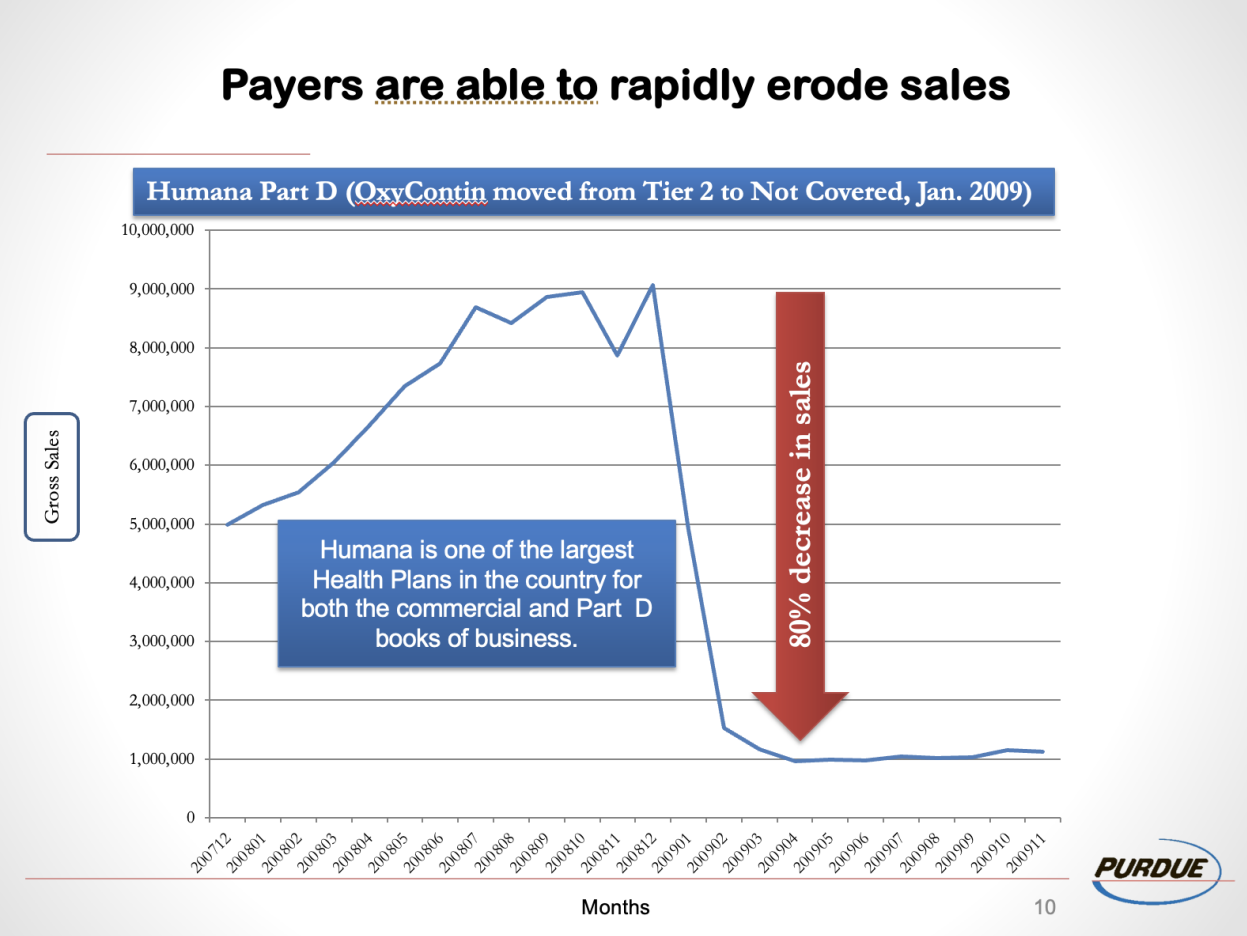
[20] E513_00006452.

246. Purdue executives did, however, recognize the substantial threat this posed to OxyContin's success—if Purdue did not take immediate action to address Medco's economic concerns it could be an existential threat to Purdue's business. Sales and marketing executive Michael Friedman (who would later become Purdue's CEO), stated, "If we do not do [demonstrate the economic value of OxyContin], I can promise you that we will eventually be shut out. . . This is a serious matter that we cannot ignore and that we must discuss . . . We cannot go on ignoring the reality of [the PBMs'] economic proof requirements . . . If we are to stay in business we need this proof of economic performance."[21]

247. Purdue's own data shows the impact that a major payor (such as Medco) moving OxyContin from a preferred formulary tier to an excluded product has on utilization:[22]

[21] E513_00045035.

[22] PPLPC030000773368.



248. Ultimately, in response to Medco's actions in 1996, Purdue determined that it needed to expand the OxyContin market by demonstrating the economic value of OxyContin in chronic non-cancer pain use to Medco and other PBMs. As Paul Goldenheim, Purdue's medical director, explained to Richard Sackler: "We have the tiger by the tail, and I wonder if we should add more muscle. Let's discuss over live sushi!"[23]

249. Importantly, had Medco in 1997—Purdue's largest customer at that time—excluded OxyContin from its formularies or put in place hard UM edits (i.e.

[23] E513_00045035.

prior authorizations) to restrict OxyContin use in non-cancer pain treatment it would have had a substantial impact on the success of OxyContin and would possibly have driven the drug off the market. Other major payors at that time, such as Cigna, had excluded OxyContin from their formularies. OptumRx (then known as Prescription Solutions) also refused to put OxyContin on its commercial formularies in 1997, due to concerns regarding the abuse potential of oxycodone (the active ingredient in OxyContin), especially considering its limited comparative effectiveness to morphine sulphate.

250. Medco, however, did not take action to exclude or restrict the sales of OxyContin. To the contrary, within three months of this exchange between Purdue executives, as detailed in this May 1997 Purdue memo, Medco had completely reversed course and "become very interested in 'partnering with Purdue'" on numerous projects to expand opioid use into the chronic pain market:[24]

[24] PPLPC025000003668.

Managed Care

To: Jim Lang
Ernie Merlino

From: Tim Richards

Subject: Medco

Date: May 4, 1997

Per our discussion on Medco on Friday, May 2, 1997 the following is a summary of information that has surfaced since the meeting with Medco in August, 1996.

* Along with Isaac Schulman, Mel Grayson has been calling on Joe DaBronzo, Pharm.D., who was promoted to Director of Utilization Management at Medco. Mr. DaBronzo feels that Medco's physician network is not properly trained on the basics of assessment and management of pain. It was Mr. Dabronzo's and Mr. Schulman's opinion that internally, Medco health care professionals needed education on pain assessment and management. Mel has set up a speaker program with Dr. Elizabeth Narcessian at Medco for May 13, 1997.

* Pertaining to discussions at the August, 1996 meeting at Medco and accentuated by Mr. DaBronzo's recent promotion, decision makers at Medco have become very interested in "partnering with Purdue" on pain assessment and management. Mr. DaBronzo is interested in developing the following materials with the help of Purdue:

    * Medco specific pain protocols for not only cancer pain, but for chronic non-malignant pain.

    * Purdue to initiate retrospective outcome pharmacoeconomic studies using and partnering with Medco data.

    * Purdue's consideration of Medco intervention for Purdue products and a negotiation of market share/performance-based contracts from this intervention.

    * Education materials (CME disease state related) for physicians, case workers, nurses and pharmacists in the Medco system.

    * Disease related patient education on pain assessment and chronic pain patient care.

With the above list, and the scheduled speaker program, Medco would like to move forward with Purdue in partnering for pain management into the future. Medco has requested of Mel Grayson for Purdue to move forward quickly in deciding whether Medco's partnering ideas are of any interest.

251. Notably, within three years of this memo, Joe DaBronzo, Medco's Director of Utilization Management, took a position as an executive director at Purdue.

252. As a first step reflecting its new "partnership" with Purdue, Medco significantly raised its quantity limits on OxyContin. As discussed above, Medco

initially implemented an 80 mg/day quantity limit at the release of OxyContin. However, within five months of the release and following further discussions with Purdue, Medco doubled it to 160 mg/day by May 1996. And by at least 2001, Medco again doubled this quantity limit and the "most restrictive [quantity limit] that Medco would recommend is for 320mg/day as per [Purdue's] platform."[25] For comparison, Express Scripts' current Advance Opioid Program has a 90 MME/day opioid quantity limit for opioid naïve patients. Medco's 320mg/day is equivalent to 480 MME/day—over *four times* the limit that Medco originally placed on OxyContin upon its release, as well as over *five times* the limit that Express Scripts now imposes on the drug.

253. This covert collusion between the PBM Defendants and the opioid manufacturers opened the flood gates to the unfettered formulary access for their opioids in exchange for rebates and other fees.

254. The PBM Defendants' influence over formulary positioning has been a key contributor to the ongoing relationship with the opioid manufacturers, because the manufacturers pay rebates and other fees based on the PBM Defendants' ability to deliver favorable drug placement within their standard formulary offerings. Because favorable formulary status is likely to increase a drug's usage and sales, and formulary exclusion (or a downgrade in formulary position) is likely to reduce a drug's usage and sales, the rebates and other fees are conditioned on a drug's formulary status. As Cottingham & Butler (a national insurance broker) noted in a client

[25] PPLPC012000064369.

presentation, PBMs have "unilateral control . . . over formularies and tiering—driving greater profits for PBMs through rebates[.]"[26]

255. The PBM Defendants and the opioid manufacturers regularly discussed and agreed about which, if any, UM measures would be utilized for particular opioid drugs.

256. As discussed above, the PBM Defendants maintain internal committees that determine which drugs are placed on their formularies. These committees are comprised of company personnel. In addition, the PBM Defendants have trade relations employees who are responsible for negotiating rebate agreements with drug manufacturers. Express Scripts refers to this committee as the Trade Relations Group and Optum refers to this committee as the Industry Relations Group.

257. Years ago, the PBMs devised and managed what were known as "open" formularies: formularies that offered varying degrees of plan coverage and benefits for virtually all available FDA-approved drugs. Consequently, with open formularies, drug companies strived to have their drugs placed by PBMs on the portion of the formulary that allowed the easiest (and least expensive) access to their drugs.

258. By the 2000s, however, the PBM Defendants began shifting to "closed" formularies as the standard offerings to their clients. "Closed" formularies provide tiered benefits, but unlike open formularies, they restrict the overall number of drugs

[26] Nancy Daas, "Prescription Drug Plan Strategies," *Cottingham & Butler* (Mar. 2017) https://www.cottinghambutler.com/wp-content/uploads/2017/03/Prescription-Drug-Strategies.pdf.

that are on the formulary. For the past two decades, most PBM covered lives have been governed by closed formularies.

259. As noted above, the PBM Defendants have greatly influenced access to opioids through formulary placement. Preferential formulary placement, such as being listed on a lower cost tier, increases a drug's utilization. Additionally, the PBM Defendants have influenced access to opioids through UM measures they utilize (or elect not to utilize) as part of their standard formularies. When implemented properly, UM measures could have restricted much of the flow of opioids entering the market.

260. Since at least 2000, opioid manufacturers have paid rebates and other fees to Express Scripts and Optum in exchange for preferred formulary placement for their opioid products.

261. The opioid manufacturers early on recognized that Express Scripts and Optum would provide unrestricted formulary status on their standard formularies in exchange for rebates and other fees. For example, in a candid February 15, 2000 email exchange, Purdue Managed Care Account Executive David Wallen explained that he could get Express Scripts "to steer [OxyContin] prescriptions" to retail pharmacies because of the rebates it received.[27] According to Wallen, "Express Scripts makes their money from the rebate, so they cannot make any money on this account if they do not get rebates."[28] In a later February 25, 2000 email, Wallen explained that Express

[27] PPLPC024000012498 (2/28/00).

[28] *Id.*

Scripts pressured its clients to put OxyContin on its formularies without restrictions: "[Express Scripts puts] pressure on [their client] to put OxyContin on formulary . . . because they make their money from rebates, and they do not get rebates if OxyContin is [subject to UM restrictions that reduce prescriptions]."[29]

262. For almost every year since 2001, Express Scripts and Medco granted OxyContin preferred formulary placement in its standard, national formularies.

263. Internal Express Scripts documents show that by 2013, some within Express Scripts believed that, with respect to OxyContin, Express Scripts was "out of alignment with the rest of the PBM/Health Plans in . . . putting this drug on a preferred tier (and) that other organizations have leaned more towards taking a harder stance on this highly abused medication."[30]

264. By the time of the Express Scripts-Medco merger, internal Purdue meeting notes reflect that in a meeting between Express Scripts/Medco and Purdue, Express Scripts/Medco representatives stated that "when Medco reviewed the drug spend for 2013, OxyContin was at the top of the list . . . *OxyContin use at Medco is out of control compared with [the other large PBMs] . . . Patients are selecting Medco because Medco [has] OxyContin in a preferred position*."[31]

265. After the merger (and years after it knew OxyContin was a heavily abused drug), Express Scripts was still pushing Purdue for more rebate dollars in

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[29] *Id.*

[30] ESI_JEFFCOMO_000265250 (4/19/13).

[31] PPLPC012000373022.

exchange for granting OxyContin preferred positions on its standard formularies. In 2014, Express Scripts reached out to Purdue requesting a higher rebate rate for OxyContin to maintain its preferred position. Purdue executives agreed given the importance of the Express Scripts relationship to OxyContin sales, stating: "[Express Scripts/Medco commercial is 20-25% of our total OxyContin gross business, and the spillover effect of a negative move by [Express Scripts] on OxyContin in 2015 cannot be underestimated . . . Given the importance and impact of this customer on OxyContin sales . . . I approve [the decision to increase OxyContin rebate rates]."[32] Express Scripts celebrated this rebate increase as a win: "we got $20M in incremental from Purdue on OxyContin . . . Not too bad considering likely not doing anything."

266. Notably at the same time (2014) that Express Scripts was pushing Purdue for more rebates to continue preferring OxyContin on its formularies, Express Scripts was also preparing the press releases and sales communications for its "Nation in Pain" report (discussed above).[33] Thus, on one hand Express Scripts was releasing a report for marketing purposes on the opioid epidemic in 2014 to "highlight the power of Express Scripts data and clinical expertise, and our commitment to identifying ways to make the use of prescription opiates safer and more effective," while on the other hand Express Scripts was receiving millions of dollars in extra rebates in order to continue to preferring the drug that started the opioid epidemic (OxyContin) on its standard formularies.

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[32] PPLPC012000475266; PPLPC035000217128; Zilocchi Dep. Ex. 13.

[33] Nowak Dep. Ex. 10.

267. Despite its knowledge of the nationwide opioid health crisis, and despite its knowledge of the impact that preferred formulary placement and the lack of UM restrictions had on increasing opioid sales, through at least 2017, Express Scripts continued granting OxyContin on the most preferred brand formulary tier, with no UM restrictions, on nearly all Express Scripts' standard formulary offerings.

268. Likewise, for most of the relevant time period, OptumRx also granted OxyContin unrestricted, preferred formulary status for most of its standard formularies. Along with the aforementioned lack of prior authorization, OptumRx refused to put effective quantity limits on opioids.

269. Up until 2017 OptumRx allowed OxyContin to have a quantity limit (QL) of four tablets a day of any strength, including 80mg strengths.

270. Quantity limits were only NDC specific, meaning a member could get the quantity limit of multiple NDCs (that is, different opioids or different formulations of the same opioid) at a time. In 2010, Purdue would still pay rebates to OptumRx so long as its covered lives were able to obtain—whether through multiple NDCs or four tablets of 80mg OxyContin a day—320mg per day of OxyContin.

271. The 320mg limit did not apply to short-acting opioids. In fact, OptumRx increased its quantity limits for short-acting opioids between 2007 and 2012. For example, the quantity limit for Opana was 12 tablets a day, or 1080 tabs for a 90 day supply. In mid-2014, Optum had the following Quantity Limits for opioids: MS Contin at 120 tablets a month, with the 200mg strength at 90 tablets a month; Nucynta 100mg at 210 tablets per month, with lesser strengths at 180 tablets per month;

Opana was 180 tablets per month; OxyContin was at 270 tablets per month. Of note is none of these opioids featured a prior authorization.

272. In 2015 and 2016, OptumRx increased the QL on United commercial plans. Hydromorphone limits were for 2mg and 4mg strengths from six to eight tablets a day; MS Contin from three to four tablets a day for the 30 and 60 mg strengths and from one to two tablets a day for the 200 mg strength due to "PA volume" to override the current QL. The morphine dose equivalent maximum was 360 tablets for United commercial plans.

273. Express Scripts and Optum have been so successful in working with the opioid manufacturers to optimize their common purpose between formulary placement/utilization management and rebates and other fees that payments have reached as high as 70% to 80% off wholesale acquisition cost for some opioid drugs.

274. To make matters worse, as the market shifted from branded opioids to generics in the mid-2000s, Express Scripts and Optum continued to grant generic opioids unrestricted and preferred placement on their standard formularies because of the profits these drugs generated for the PBM Defendants through spread pricing and in other ways. Indeed, OptumRx's own internal presentation from 2013 touts generic utilization as a "high driver of revenue and profit," even more so than brand rebates.[34]

275. Thus, from the late 1990s through 2018, Express Scripts, Medco, and Optum granted both brand and generic opioids, including OxyContin, preferred

[34] OPTUMRX_JEFFCO_0594849.

positions on its standard formulary offerings, which was critical to the success of the opioid manufacturers increasing utilization and expanding the opioid market both nationally and in Plaintiff's Community.

2. The PBM Defendants and the Opioid Manufacturers Used Parity to Limit the Use of Utilization Management Measures for Opioids

276. If they had been implemented earlier, the PBM Defendants' UM measures would have helped control the flow of opioid drugs into every community in America. These measures include days' supply quantity and daily dosage limits, refill-too-soon limits, prior authorizations (which require additional approval before drug is dispensed) and step edits (which could require that a patient try a different, safer drug before being given a more dangerous one).

277. The PBM Defendants, however, have financial incentives to give opioids preferential treatment relative to other methods of treating pain (including non-pharmacological methods), and these incentives have made them less likely to mitigate inappropriate opioid usage. While the PBM Defendants have represented that they use UM measures to ensure only the safe and effective use of pharmaceuticals, behind closed doors they had entered into confidential agreements with the opioid manufacturers to bargain away the use of these measures which would have limited dispensing to only medically appropriate uses.

278. Instead of placing limits on the inappropriate use of these dangerous drugs, the PBM Defendants bartered the use of UM measures which would have

helped control the widespread abuse and diversion of opioids in Plaintiff's Community and in communities throughout the country.

279. Throughout their confidential negotiations with the opioid manufacturers, in exchange for rebates and other fees, the PBM Defendants have agreed that they would not "disadvantage" their opioid drugs, nor would they place UM restrictions on their use within their standard offerings. Effectively, this has meant that the PBM Defendants have bartered away application of UM measures, which opened the floodgates to these dangerous drugs. Thus, the parties agreed that none of the opioid drugs would be disadvantaged and that they all would have the same UM restrictions as other drugs that did not have the propensity for abuse inherent in opioid drugs. These parity and "no disadvantage" contract terms had the effect of the PBM Defendants and the opioid manufacturers sharing a common purpose of ensuring the unfettered access to opioids across the entire class of opioid drugs.

280. Express Scripts' standard rebate agreements defined the term "disadvantage" as any time when the opioid manufacturer's product is "subject to prior authorization, NDC blocks, counter-detailing, co-pay differentials, or a step edit that negatively had to have affects the reimbursement and/or Formulary status of the Product as compared to other products in its designated [competitive product category] . . . ."[35]

[35] ESI_JEFFCOMO_000250248 (1/1/16).

281. Optum's template rebate agreements had similar language tying payment of rebates to common treatment of all other opioids in the formulary's therapeutic category. Its agreements' language stated that rebates would only be payable if the opioid manufacturer's product is not "subject to Disadvantaging including, but not limited to: prior authorization, NDC blocks, counter-detailing, co-pay differentials, dispensing restrictions, or endorsed targeted messages (electronic edits)."[36]

282. Express Scripts and Purdue's 2002 contract included language stating Purdue would not pay rebates if its opioids were restricted. Likewise in 2009, Purdue would only pay rebates if its opioids were "unrestricted on the preferred brand tier." Again in 2014, Purdue would only pay rebates on OxyContin if it was on "lowest preferred brand tier, without restrictions, including no prior authorization or step therapy." Even as late as 2016, Express Scripts acknowledged that if it tried to put any restrictions on OxyContin (such as restricting opioid use to acute pain, blocking opioids unless the use was for cancer or other approved uses, or requiring prior authorization) that it would violate its rebate agreements with Purdue and would result in a loss of rebates.

283. Another example occurred in 2010. During negotiations between Janssen and Medco (Express Scripts' predecessor) regarding the formulary placement of the fentanyl drug Nucynta, the parties agreed Janssen would only pay rebates so long there were no step edit restrictions and agreed that Nucynta would

[36] OPTUMRX_JEFFCO_0000473712 (3/20/14).

be protected from "being disadvantaged vs. any branded agent in our defined market basket" of short-acting opioid ("SAOs").[37]

284. Likewise, in 2012 negotiations between Express Scripts and Endo the parties agreed that "Endo Products are 'not disadvantaged to any other brand name pharmaceutical product in the same [competitive product category]'" and that this disadvantaged language meant any UM restrictions must apply to all products in the competitive class.[38]

285. The same parity terms are included in Optum agreements. For example, the 2011 Rebate Agreement between OptumRx (then known as Prescription Solutions) and Johnson & Johnson for Nucynta (and other J&J drugs) required that it not be "disadvantaged as compared to other Branded or specialty Drugs within the Manufacturer Drug's Defined Drug Market . . ."[39]

286. The 2012 Catamaran (now part of OptumRx) rebate agreement with Reckitt Benckiser for Suboxone Film required that it "not be subject to Disadvantaging including, but not limited to: prior authorization, NDC blocks, counter-detailing, co-pay differentials, dispensing restrictions, therapeutic conversion programs, therapeutic substitution, other access or reimbursement restrictions, or endorsed targeted messages (electronic edits)."[40]

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[37] JAN-NYDFS-00001455181 (2/25/10).

[38] ENDO-OPIOID_MDL-07228036 (4/22/10).

[39] OPTUMRX_JEFFCO_0000006804 (1/1/11).

[40] OPTUMRX_JEFFCO_0000473712 (3/20/14).

287. Likewise, in 2012 negotiations between OptumRx and the drug maker Covidien with regard to tiering of its opioid drug, the parties agreed to use the OptumRx "boilerplate disadvantaging language."[41]

288. The same was true for Teva's 2015 agreement with OptumRx, which required unrestricted access and "parity" between its fentanyl drug Fentora and other drugs in its "Defined Drug Market," meaning that there would be no prior authorization limits unless it is applied to all "competing drugs" as well.[42]

289. The 2016 agreement between OptumRx and Depomed with regard to Nucynta required that "[p]rior authorization shall not be allowed unless applied to all other single source branded Drugs in the Defined Drug Market that are on Formulary . . . ."[43]

290. The lockstep parity terms that each PBM Defendant and opioid manufacturer negotiated served and furthered the common purpose of the Formulary & UM Enterprise (described in greater detail below) because it normalized the use of UM measures across the entire class of opioids and guaranteed that the overall market for prescription opioids would not diminish because of utilization management. The rebate agreements conditioned payment on each opioid manufacturer not being disadvantaged with regard to applying UM measures unless the entire market basket of all competing drugs was treated the same. The parity

[41] OPTUMRX_JEFFCO_0000140266 (6/1/12).

[42] TEVA_CAOC_08826718 (1/12/17).

[43] OPTUM_JEFFCO_0000011106 (4/1/16).

terms therefore ensured that no single opioid manufacturer would be disadvantaged against the other and then, each could be free to compete outside of the Formulary & UM Enterprise for market share of their drug within the fraudulently increased system. The opioid manufacturers knew that UM presented a slippery slope—if more UM were employed, it would ultimately lead to the adoption of restrictions across the entire class of drugs.

291. Indeed, this is precisely what happened. As summarized in a 2017 Express Scripts document, "Opioid management is currently a hot button issue. Express Scripts clients are demanding a solution as CMS and states implement requirements around appropriate opioid management (i.e. 3 states took action on prescriber 1st fill day supply restrictions; 12 additional states in process of implementing restrictions around morphine equivalent dose edits etc.) . . . We anticipate our opioid retail margin to be at risk over the next two to five years as states and federal government continue to intervene and prescribing practices change."[44] This was obviously a significant issue to Express Scripts, which made roughly $60 million in margin on opioids in 2016.

292. As alleged more fully herein, each member of the Formulary & UM Enterprise thus conducted and participated in the conduct of their enterprise through a pattern of racketeering activity—including mail and wire fraud—in which they formed a common purpose of growing the unfettered use of opioid drugs.

[44] ESI_JEFFCOMO_000029922 (3/9/17).

3. The PBM Defendants Misrepresented that They Were Using Their Formularies to Promote Safe Use and Appropriate Prescribing of Opioids

293. Rather than provide transparency into their dealings with the opioid manufacturers, Express Scripts and Optum represented to their clients, patients, and the public that they used their market power to design formulary offerings to promote the safe use and appropriate prescribing of opioids. These representations were false. Express Scripts and Optum instead have constructed standard formularies that garnered significant rebates and other fees in exchange for often unfettered access for "preferred" opioids.

294. For years the PBMs have represented that they promote better health and are dedicated to making the use of prescription drugs safer. For example:

- For years between 2000 and 2010, Express Scripts represented in its SEC filings that it "works with clients, manufacturers, pharmacists and physicians to . . . improve members' health outcomes and satisfaction."
    - During these same years, Express Scripts also represented in its SEC filings that it "is a company dedicated to making the use of prescription drugs safer and more affordable for plan sponsors and over 50 million members and their families."
- During the same time period Medco represented in its SEC filings that "[Medco] capitalize[s] on our clinical expertise and advanced information technology infrastructure . . . to improve safety and the quality of care for patients. We do this by developing action-oriented clinical programs and services based on clinical rationale. . ."
- In its 2008 annual report, Medco represented that "[a]t Medco innovation, precision, and advocacy are in our DNA. We strive to make all of medicine smarter and as a result make healthcare better."
- In a 2013 interview, Express Scripts CIO Gary Wimberly represented that "by filling 1.4 billion prescriptions per year, we have over 10 petabytes of useful data from which we can gain insights and for which

we can develop solutions . . . [to] improve the health of patients." In addition, Mr. Wimberly stated, "[Express Scripts] has researchers and scientists whose sole job is to interpret and analyze the data to identify opportunities to improve health outcomes."

- In 2002 Prescription Solutions represented in public filings: "We recognize the treatment value of prescription medications. Our goal is . . . to increase the appropriate use of prescription medications. Getting the right medication to the right person at the right time is the best approach for everyone concerned."

- In 2007 Prescription Solutions represented – "Our goal is to promote the appropriate use of prescription medications. By focusing on clinical quality and total patient care, we help our clients and members improve outcomes."

- In its 2008 Annual Report, Optum represented– "Beyond the data and technology, and beyond the numbers and networks, our businesses are made up of people who strive, every day, to fulfill our mission by helping people live healthier lives."

- UnitedHealth Group's 2009 Annual Report stated "Information technology has the power to transform health care. UnitedHealth Group built a $2 billion business, Ingenix [OptumInsight predecessor], around that idea. Ingenix is committed to using the power of health information and analytics to help save lives, improve care and modernize the health care system."

- In UnitedHealth Group's 2011 Annual Report it stated "OptumRx is dedicated to helping people achieve optimal health . . . improving quality and safety, increasing compliance and adherence, and reducing fraud and waste."

295. Similarly, in a September 2013 letter to the Pennsylvania House of Representatives Committee on Health, Express Scripts stated that "[o]ur company's mission is to make prescription drugs safer . . ."[45]

[45] Letter from David Dederichs, Sr. Dir. Express Scripts to Matthew Baker, Pennsylvania House of Representatives, Comm. on Health, *Re Opposition to HB*

296. Likewise, OptumRx's parent company, UnitedHealth Group, represented in its 2013 Annual Report that "UnitedHealth is advancing strategies to improve the way health care is delivered and financed . . .."[46]

297. In a 2013 interview, Express Scripts CIO Gary Wimberly summed it up: "Everything we do every day focuses on health outcomes."

298. As alleged more fully herein, despite the PBM Defendants' acknowledgement that they are supposed to construct formulary and UM offerings that promote safe and affordable drugs for their members, the PBM Defendants have not actually done so. To the contrary, the PBM Defendants have used their power to negotiate rebates and other fees, to control the offered formulary structures, to refrain from implementing or offering UM measures, all in an effort to allow the opioid manufacturers unfettered access to their formularies so that the number of opioids prescribed and sold could continue to grow and generate more profits for the PBM Defendants and the opioid manufacturers, thereby bringing the opioid epidemic to the doorstep of nearly every household in America.

746, at 1 (Sep. 4, 2013) https://www.legis.state.pa.us/WU01/LI/TR/Transcripts/2013_0159_0011_TSTMNY.pdf.

[46] UnitedHealth Group 2013 SEC Form 10-K, at p. 2 (Dec. 31, 2013) https://www.sec.gov/Archives/edgar/data/731766/000073176614000008/unh2013123110-k.htm.

B. During the Early Years of the Epidemic, the PBM Defendants Conspired with the Opioid Manufacturers to Expand the Opioid Market and Increase Opioid Utilization

299. Not content merely to *permit* access to opioids, the PBM Defendants colluded with opioid manufacturers affirmatively to increase opioid prescribing. Since the release of OxyContin, the PBM Defendants have conspired with Purdue in several crucial ways to expand opioid market and increase the sales and prescribing of OxyContin.

300. Medco partnered with Purdue on therapeutic exchange programs to increase OxyContin utilization during the years immediately following the drug's release. For example, in 1997-1998, Medco worked with Purdue to develop a "switch program" where pharmacies would switch out a competing product for OxyContin at the pharmacy counter. Purdue executive Michael Friedman explained the value of this program: "Medco is a huge customer and the potential gain from this effort could dwarf that of many other opportunities."[47]

301. In addition, during key years in the growth of OxyContin utilization, Medco also worked with Purdue "behind the scenes" to get large health plans to lift restrictions—such as prior authorizations and quantity limits—on OxyContin utilization. For example, a 2002 email reveals Medco and Purdue working together to prevent the implementation of a prior authorization (PA) that would have reduced the supply of opioids:[48]

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[47] E513_00022558.

[48] PPLPC029000064034 (3/13/02).

To: Radlund, Julia[/O=PURDUE/OU=PURDUE US/CN=Sales and Marketing - Field/cn=DCB07D6C]
Cc: Nagorski, Lynn[/O=PURDUE/OU=PURDUE US/CN=Sales and Marketing - Field/cn=9F4581F2]; Richards, Tim[/O=PURDUE/OU=PURDUE US/CN=RECIPIENTS/CN=CBCEAB1F]
From: Grayson, Mel
Sent: Wed 3/13/2002 9:31:10 PM
Subject: Concerns at MMMC

To All;

I met today with Ed Adamcik of MMMC. His major concern is to negotiate a new rebate contract. Ed says that the reason they have been able to keep various clients from placing a PA on Oxy has been the value of the rebates to them. If this is suddenly reduced, there may be more clients who might want to place a PA, or some other type of restriction on OxyContin.

302. To that end, in a telling exchange in 2002, when Highmark Blue Cross Blue Shield decided it would put a 300mg daily limit on OxyContin, Medco pushed back because this meant that Medco would lose rebates from Purdue. At the time, Purdue warned Medco that "[o]ur platform for rebates is to permit the patient to reach 320 mg/day of OxyContin," so if Highmark adopted a 300mg a day limit, Medco "will be loosing [sic] rebates for a mere 20mg/day differential." In order to rectify the situation, Ed Adamcik, Medco's Vice President of Contracting, then intervened and convinced Highmark to drop its daily dosage limit.

303. During this same time period, internal Purdue emails show how the data that Purdue received from Medco helped eliminate potential UM restrictions and further strengthen the partnership between these two companies. In 2003, Purdue's Medco Account Representative Bernadette Katsur stated:

> "I do see tremendous value in the data that [Medco] is willing to provide. As he explained to me the large MCO's could be identified by number, and then he would be willing to discuss opportunities or concerns on a plan sponsor by plan sponsor basis. He would then be willing to work with me to develop individualized strategy for that account. That would mean pulling in Medco Client Manager as well as the local account executive. This type of working relationship has proven to be extremely successful with AdvancePCS. *We have eliminated many attempts to*

> *[prior authorization] and place [quantity limits] on product through this type of process. We have not had that degree of intimacy with Medco, and I think that Ed [Adamcik] would be willing to take that leap with the understanding that the extra percentage is being paid for that purpose*."[49]

304. An exchange between Medco, Medco's largest client (UHC), and Purdue that same year, 2003, exemplified the ideas in Ms. Katsur's email above. In early 2003, Medco worked again behind the scenes with Purdue to convince UHC to double a contemplated quantity limit from 60 tablets per prescription to 124 tablets per prescription. Given the amount of OxyContin that was sold through UHC plans in 2003 and the years thereafter—both nationally and in Plaintiff's Community—convincing UHC to double its quantity limit to 124 tablets likely resulted in a substantial increase in OxyContin sales during crucial years when the opioid epidemic was taking hold.

305. Rather than implement standard protocols that they knew would limit OxyContin to narrow, appropriate usage, the PBM Defendants engaged in a pattern of deception (working in conjunction with the opioid manufacturers and often using manufacturer-created data and information) in order to increase opioid utilization and their own profits.

C. For Two Decades after the PBM Defendants Knew the Opioid Epidemic Was Occurring, the PBM Defendants Continued to Conspire with the Opioid Manufacturers in the Deceptive Marketing of Opioids

306. Beginning the late 1990s, opioid manufacturers—including, but not only Purdue—engaged in a multifaceted campaign to expand the opioid market by

[49] PPLPC012000067648 (emphasis added).

creating and disseminating misinformation about the safety and efficacy of opioids used in chronic pain treatment and the risks of opioid addiction.

307. The PBM Defendants knew that there has never been reliable evidence demonstrating opioids were safe or effective at treating chronic pain long term. The PBM Defendants further knew that opioids, particularly when used long term to treat chronic pain carry serious risks of addiction. And yet, starting shortly after the release of OxyContin and continuing for years after the opioid epidemic was spreading throughout the country, the PBM Defendants worked with the opioid manufacturers in numerous capacities in furtherance of these efforts. In particular: (1) the PBM Defendants disseminated the opioid manufacturers' false messages about chronic pain and addiction to high prescribers and patients, and (2) the PBM Defendants provided research, data, and consulting services to the opioid manufacturers to assist in expanding the opioid market.

308. As one type of example, PBM Defendant Express Scripts (along with its subsidiaries – e.g., Express Scripts Specialty Distribution Service; Express Scripts SDS; HealthBridge, United BioSource LLC; Curascript, Inc.) partnered and/or collaborated with opioid manufacturers (e.g., Purdue, Endo) on Patient Assistance Programs ("PAPs") – which provide free or low-cost medications to eligible individuals based on factors such as low-income and/or lack of health insurance. PAPs are "a

triple boon for manufacturers" as they "increase demand, allow companies to charge higher prices, and provide public-relations benefits."[50]

309. For more than two decades, from the mid-1990s through 2017, Express Scripts and/or its subsidiaries partnered and/or collaborated with Purdue on its PAP - which is significant in multiple respects: a) as Purdue's partner mail order pharmacy, Express Scripts dispensed 100 million+ opioid pills specifically for Purdue's PAP and it repeatedly did so in violation of the Controlled Substances Act ("CSA") (as discussed in greater detail below); b) since 2002 Express Scripts also administered Purdue's PAP, further establishing its collaboration and critical role in this early, continuing, and very successful marketing effort to increase utilization, drive volume, and facilitate access relative to OxyContin and other Purdue opioid products; and c) as a result of Express Scripts' integral involvement with Purdue's PAP, it was well aware of the addiction, abuse and diversion issues surrounding OxyContin and other opioids since the mid-1990s.

310. Express Scripts and/or its subsidiaries played multiple roles (e.g., partner mail order pharmacy, program administrator, etc.) in Purdue's and Endo's respective PAP marketing schemes. The importance of Express Scripts is evident from internal emails. For example, a 1996 email outlined how Purdue's "IPAP useage[sic] has sky rocketed since [Purdue] instituted the Express Script policy,"

[50] Howard, David H., *Drug Companies' Patient-Assistance Programs – Helping Patients or Profits?* New England J. Med, 97, 97-99 (2014), *available at* https://www.nejm.org/doi/pdf/10.1056/NEJMp1401658.

noting that "utilization has nearly quadrupeled[sic]."[51] In a subsequent email in the chain, a Purdue employee stated that "Express Scripts has made it much easier to get the free product, thus, some may be using it that wouldn't be before. For example, I can remember several instances where we were having difficulty getting retailers to participate in the program before Express Scripts."[52] Moreover, as a result of Express Scripts' collaboration and work, Purdue's and Endo's respective PAPs were highly successful in increasing utilization, driving volume, and facilitating access relative to Purdue's and Endo's opioids, especially OxyContin and Opana.

311. The PBM Defendants' participation in the increasing opioid utilization and the fraudulent marketing of opioids continued even after Purdue pleaded guilty to criminal misbranding of OxyContin in 2007, as described above. Thus, even after Purdue acknowledged the falsity of its claims, the PBM Defendants, in collaboration with opioid manufacturers including Purdue, continued to spread the same misrepresentations about the safety and efficacy of opioids.

312. The PBM Defendants' participation in the fraudulent marketing of opioids continued long after their own data told them that the huge increases in opioid prescribing were creating a crisis of addiction, overdose, and death across the United States.

313. Regardless of what the PBM Defendants knew or did not know at the outset of their marketing activities, they continued to engage in fraudulent marketing

[51] PPLPC008000000530.

[52] *Id.*

of opioids long past the point where they had actual knowledge of the falsity of the representations they were disseminating.

1. The PBM Defendants Disseminated the Opioid Manufacturers' Deceptive Propaganda

314. Starting in the late 1990s—after granting Purdue's opioids preferred, unrestricted formulary placement in their standard offerings—the PBM Defendants partnered with Purdue and other opioid manufacturers to spread false information about opioids in order to increase opioid sales and expand the market.

315. For example, in 1999, Medco arranged for its pharmacists to be trained by Purdue's speaker consultants regarding chronic pain management and the use of OxyContin.

316. In 2003, internal Purdue documents show "[o]pportunities have been presented by Medco to work more closely with targeted clients within the marketplace on a client-by-client basis." These "opportunities" included developing educational programs to "stave off any formulary restrictions," disseminating Purdue created "educational" materials—including "New Perspectives on the Pharmacology of Opioids and Their Use in Chronic Pain" and Drug Diversion and Abuse: The Facts, Legal and Ethical Issues Affecting Pain Management: Fact or Fiction." Purdue provided this information to Medco to "be used with employers and managed care plans on the appropriate utilization of [Purdue's] products."[53]

[53] PPLPC012000064369.

317. During these same years, along with Medco, Express Scripts was also one of Purdue's largest customers. Notably, Medco and Express Scripts remained Purdue's largest customers for OxyContin for the years up to and following the 2012 merger of these companies.

318. And in similar fashion to Medco, Express Scripts also worked directly with Purdue in the critical years of OxyContin growth to expand the pain treatment market through the dissemination of misinformation about the use of opioids to treat chronic non-cancer pain.

319. For example, in 2000 and 2001, Express Scripts worked together on numerous programs to disseminate "educational" materials to tens of thousands of patients and high prescribers of OxyContin advocating for opioids in chronic pain treatment and downplaying the risks of addiction. These programs included Express Scripts engaged in mass mailings of Purdue created propaganda such as "Dispelling the Myths about Opioids," "The Impact of Chronic Pain: An Interdisciplinary Perspective CME booklet," "Overcoming Barriers to Effective Pain Management," and "Use of Opioids in Chronic Noncancer Pain CME booklet."[54] These documents contained false information downplaying the risk of addiction and promoting the use of opioids in long term chronic pain treatment.

320. In one particularly telling internal Purdue "call note," a Purdue executive discussed "developing a piece on Opioid guidelines, [New England Journal

[54] PPLPC029000016774; PPLPC029000020703; PPLPC009000021694; PPLPC009000021695; PPLPC029000040033; PPLPC029000040028.

of Medicine (NEJM)] quotes, and addiction terms." Notably, the "NEJM quotes" likely refer to a one-paragraph letter that was published in the *New England Journal of Medicine* reporting an observed low rate of addiction in patients prescribed opioids for short periods in an in-patient hospital setting. (Purdue and other opioid manufacturers misrepresented this letter as a "study" and claimed that it demonstrated that the risk of addiction to opioids was low when the drugs were prescribed for long-term, outpatient use.) The Purdue executive continued: "[l]egal has stated that [Purdue] representatives cannot utilize this [NEJM] piece. My thoughts are that this piece may be sent out by Express Scripts. Express Scripts and Purdue could target [family practitioner physicians and internal medicine physicians] who are the high writers of [DEA Schedule II and III drugs]. The mailer was intended to educate the physician on the beneficial uses of OxyContin and the preferred formulary status."[55]

321. A number of these joint programs between Express Scripts and Purdue were prompted by Express Scripts' desire to work with Purdue to address the negative attention that OxyContin was receiving related to abuse and diversion in the early 2000s. For example, a March 14, 2001 letter from Express Scripts to Purdue explained "[c]learly with the market turbulence surrounding OxyContin you and your organization have significant demands on your time . . . there are several strategic initiatives where Express Scripts can support Purdue Pharma in your efforts to

[55] PPLPC009000021694; PPLPC009000021695.

educate the market on the prescribing, administration and consumption of OxyContin."[56]

322. These "strategic initiatives" proposed by Express Scripts included sending 15,000 "targeted" mailings to physicians which included a letter written by Express Scripts' Medical director summarizing key principles of the Purdue front group, American Pain Society, and included the Purdue-created brochures "The Patient Bill of Rights for Pain Management" and "Dispelling the Myths about Opioids" which contained misinformation about OxyContin risks, such as "addiction risk also appears to be low when opioids are does properly for chronic noncancer pain."[57]

323. An April 2001 Purdue memo further described the reasons behind Express Scripts and Purdue's collaborations at that time: "[Express Scripts] has told us that this mailing is necessary so that [Express Scripts] may squelch the anti-OxyContin pushback from their clients (Managed Care Organizations and Employer Groups) due in large part to the national media attention OxyContin is receiving."[58]

324. Purdue's and Express Scripts' joint efforts to expand the opioid market continued in the summer of 2001, when they used an Express Scripts "proprietary database" to identify the top 1,900 physicians with high prescribing rates for Schedule 2 narcotics and then mailed these 1,900 physicians materials created by the

[56] PPLPC028000031679.

[57] PPLPC028000031679.

[58] PPLPC029000040033; PPLPC029000040028.

front-group American Pain Society ("APS"). The mailed APS material promoted use of pain scales and the debunked, industry-advocated concept of pseudo-addiction.

325. Express Scripts and Purdue's collaboration continued through 2004, when Express Scripts and Purdue developed a series of pain management presentations for an Express Scripts' clients, to be conducted by Purdue's Medical Liaisons, who were doctors and medical professionals employed by Purdue to promote opioid therapy.

326. During these same years, Purdue also conspired with Optum to spread misinformation about the use of opioids to treat chronic pain and the risks of opioid addiction. One example occurred in February 2003, when UHC and OptumInsight met with Purdue to give a presentation on "Managing Chronic Pain Associated with Lower Back Pain." The goal of this presentation was to develop a comprehensive plan between Purdue, UHC, and OptumInsight to re-educate physicians on opioid use for the treatment of chronic pain and low back pain. The program included "[t]argeting physicians not aligning with UHG clinical objectives [for treating chronic pain] to modify behavior."

327. As a result of this meeting, in 2004 OptumInsight and Purdue executed a Master Services Agreement to roll out this program in 2004-2005. The program would include Purdue, UHC, and OptumInsight working together to identify physicians from UHC and OptumInsight's database and then developing comprehensive education materials on the effectiveness of opioids in chronic pain treatment to send to these physicians.

328. OptumInsight and Purdue delivered this information through a series of teleconferences, newsletters, faxes, live meetings, case study monographs, letters, and website and web-based programming directly to physicians.

329. The project, referred to as the United Healthcare Physician Education program, included the following false and misleading messages targeted at UHC prescribing physicians:

- Opioid use is associated with some moderate side effects, but the risk of drug dependence is low;
- Concerns about abuse, addiction, and diversion should not prevent the proper management of chronic and low back pain;
- Opioids are the most effective way to treat pain;
- Opioid addiction does not occur in the chronic pain patient; and
- Certain signs of dependence that sometimes can be confused with addiction are actually "pseudoaddiction."

330. To assist in the marketing efforts of opioid manufacturers, Express Scripts and Optum have for years provided multiple opioid manufacturers with lists of all their plan clients as well as the names of physicians who were participating in the plan's provider networks. The manufacturers used this information to target the highest opioid prescribers with pull-through marketing.

331. For example, according to one 2011 email, Endo sales representatives were instructed to "[m]aximize pull-through with key managed care plans," "[d]rive brand awareness across top [Opana ER] prescribers," and promote favorable Opana

ER formulary positioning.[59] Sales representatives were also told to focus on providers "that have the most potential" and not "waste time" on other physicians.[60] Sales representatives also were dispatched to (and did) promote Opana ER formulary status to prescribers.

332. In another example, after Endo had negotiated a favorable Tier 2 formulary deal with Optum in 2010, sales representatives were told to "present the great information" to prescribers and take advantage of the Opana ER "opportunity" for "pull through" sales.[61]

> **4. Only when all this is done should you present the great information that now,** OPANA ER is 2T, Lowest Branded Co-Pay for UHC Commercial (and Part D) patients! **Get commitment first that OPANA ER is the right choice…then show how easy it is to provide OPANA ER for these patients!**

333. In addition, beginning in 2006, Express Scripts and Purdue entered into an ongoing "Participating Manufacturer Agreement" under which, in return for "administrative fees," Express Scripts would [redacted] Express Scripts would also [redacted] And, Express Scripts agreed it would provide numerous deliverables to Purdue, including

[59] ENDO_OPIOID_OHAG-00030138 (1/14/11).

[60] ENDO_TXMDL_00448429 (10/4/09).

[61] ENDO-OPIOID_MDL-00719759 (3/3/10).

[redacted] which enabled Purdue to more effectively pull through its drugs' formulary status to physicians. The "administrative fees" Express Scripts received were tied to the number of opioids it sold—*i.e.*, the more opioids it sold, the more it made. This agreement was strictly confidential. Express Scripts and Purdue renewed this agreement on at least three occasions, and it was in place until at least the end of 2010.

334. In 2011 and 2012, Express Scripts and Purdue collaborated on false and misleading guidelines for workers' compensation patients to promote "safe and effective chronic opioid therapy."[62]

335. In fact, as late as 2017, Express Scripts gave educational presentations on pain management that treated the risk of addiction to opioids as minimal. In a presentation regarding "The Management of Persistent Pain in Older Persons," Express Scripts Vice President Andrew Behm asserted that psychological dependence to narcotic analgesics was "rare" and that "Addiction associated with the appropriate use of opioid analgesics is uncommon."[63] The presentation also described "physical dependence" as "common" and a "state of adaptation to chronic opioid therapy," and recommended fentanyl for chronic pain in older adults.[64]

336. OptumRx also participated in a Purdue advisory board in 2013 for the "abuse deterrent" version of OxyContin, which was focused on payers in managed

[62] *See* PPLPC012000368690 (3/8/12); PPLPC012000368687 (3/8/12).

[63] ESI_JEFFCOMO_000012632, at slide 56 (4/24/17).

[64] *Id.*

care.[65] In 2016, OptumRx conducted studies for Purdue to assess the economic impact of reformulated OxyContin.

337. OptumRx affiliates also marketed their data analytics capabilities to Purdue for research projects related to opioids, proposing, for example, to sell medical and pharmacy claims data from its "Cliniformatics DataMart" to Purdue, to study patient disenrollment in Medicare Advantage plans that discontinued coverage of OxyContin ER, and to research overdoses associated with OxyContin.

2. The PBM Defendants' Affiliated Entities Provided Research, Data, and Consulting to the Opioid Manufacturers to Expand the Opioid Market

338. In addition to assisting the opioid manufacturers in spreading false information about opioids, for years the PBM Defendants and their affiliated companies provided the manufacturers with data, research, and consulting services needed to expand the opioid market.

339. For example, in the late 1990s and early 2000s, Express Scripts' affiliate research entity, Practice Patterns Sciences, Inc. ("PPS"), and Medco's Institute for Effectiveness Research provided research and studies for Purdue in to aid its efforts to expand the opioid market. One example occurred in 2001, when Express Scripts/PPS developed a study for Purdue on "The Value of OxyContin Therapy in Patients with Moderate to Severe Pain due to Osteoarthritis."[66]

[65] PPLPC001000139198; PPLPC019000857218.

[66] PDD8801105525.

340. In addition, from the early 2000s until 2015, OptumInsight, a sister company of OptumRx, also helped Purdue generate clinical studies, educational materials, and marketing programs to downplay the addictive properties of OxyContin and expand its use throughout the country.

341. In order to do so, OptumInsight was paid by Purdue to reverse engineer studies to achieve desired outcomes; create algorithms to identify potential pain patients to suggest OxyContin prescriptions; and create large-scale marketing plans to convince payors that long-term opioid usage was not only useful for many types of pain and did not lead to serious addiction for long-term opioid users.

342. For example, in 2000 and 2001, OptumInsight (then known as Ingenix) worked with Purdue to develop algorithms and studies to identify chronic pain patients. One was an algorithm that would mine UHC's claims data called "the chronic pain patient identification algorithm."[67] The other was called "Profiling the OxyContin Patient."[68] The purpose of this study was to assist Purdue in shifting formulary discussions with PBMs/health plans from a purely per-member fiscal discussion to an overall "clinical and fiscal" benefits discussion. Purdue paid for this study, in part, to counter the recent focus in the market on "cases of diversion" and "premium pricing" of OxyContin. Purdue's goal of this study was to use the OptumInsight's "data/evidence" to demonstrate from a payer and patient perspective

[67] PPLPC028000016640.

[68] PKY181047060.

the clinical/financial benefit of OxyContin given the overall costs associated with the undermanagement of pain.

343. In October of 2002, OptumInsight proposed a "Chronic Pain Management" study and education initiative to present a series of teleconferences to providers in the UHG/UHC network. The purpose of this educational initiative was to "optimize patient care in the treatment of chronic pain." One of the themes of this report is that "[m]ost specialists in pain medicine and addiction agree that patients with prolong opioid therapy . . . do not usually develop addictive behavior" and to convince the providers that "[o]pioids are effective, have a low addiction potential, and may have fewer long-term side effects than other pain treatments."[69]

344. This clinical initiative was launched by UHG that same year; UHG requested $200,000 to implement the initiative and begin targeting plans for the program. Purdue stated that while that was a big investment, that the return would be high. The study did with UHG proved overall to "significantly improve the relationship with this client" and would "provide outcomes data that can prove valuable in the future with regard to placement and pull-through for United and other major HMOs."[70]

345. In February 2003, UHC threatened to implement a stricter quantity limit on OxyContin and other Purdue products. Purdue worked with OptumInsight

[69] PPLPC036000014773.

[70] PPLPC035000032658.

to provide "new data" for June 2003.[71] Based on the joint efforts of Purdue and OptumInsight, UHC subsequently doubled its quantity limit (to a level that Purdue stated was high enough that it should not affect OxyContin sales).

346. In March of 2005, OptumInsight prepared an Executive Summary to Purdue for "A Usual Care, Multicenter, Open-label, Randomized, 4-month Parallel Group Trial to Compare the Impact of Therapy with OxyContin on Health Outcomes and Research Utilization in Subjects with Moderate to Severe Osteoarthritis Pain of the Hip or Knee." The purpose of the study was to present evidence to "health-system decision-makers" of the cost effectiveness of treating osteoarthritis with OxyContin.[72] OptumInsight went on to present this study on behalf of Purdue at the International Society for Pharmacoeconomics and Outcomes Research annual meeting in 2005 where it won an award.

347. Because these studies were reverse engineered and constructed in order to advance Purdue's market share of OxyContin, in certain instances, members of the medical/health care community pushed back on Purdue's and OptumInsight's joint medical journal publications. When that occurred, the two companies worked together to respond.

348. From 2011 through at least 2015, Purdue and OptumInsight worked together to build a comprehensive, multi-step "aspirational statement" and

[71] PPLPC012000057093; PPLPC012000057095.

[72] PPLPC018000065660 (this study was performed by Innovus Research Inc. As noted above, Innovus subsequently merged with Ingenix and then later was renamed "OptumInsight").

"evidence-generated" strategies for Butrans, OxyContin, Intermezzo, Targin, and hydromorphone.[73] The goal of this coordinated effort was to identify the best way to position these drugs with the public, patients, providers, and payors to increase utilization and maximize sales.

349. The first phase occurred in April 2012. It included a "Product Review" for each Purdue drug to "complete a focused review of product, literature, and on-line information to establish the likely interplay between the product, competitors, and the market access and reimbursement environment."[74]

350. The second phase occurred simultaneously in April 2012 and included "Event Mapping" which was an in-person workshop for the "Satellite [Purdue-OptumInsight] Team." The purpose of Event Mapping was to identify "significant events that will affect future evidence generation strategies."[75]

351. The third phase occurred in June 2012; it was called the "Aspirational Value Proposition" phase. During this time, the group would create the "ideal value proposition statement" which "is concise, appeals to payers' strongest decision-making drivers and is evidence based to: (1) identify the burden and unmet need that OxyContin will fulfill; (2) describe the solution provided by OxyContin compared to existing treatments; (3) describe the risks of OxyContin compared to existing

[73] The examples below represent OptumInsight's effort with respect to OxyContin. OptumInsight produced similar documents for Purdue for Butrans, OxyContin, Intermezzo, Targin, and Hydromorphone.

[74] PPLPC019000666914.

[75] PPLPC019000665555; PPLPC019000665974.

treatments; and (4) delineate the economic benefit of OxyContin compared to existing treatments." OptumInsight's OxyContin "value statement" was targeted at moderate to severe pain and to endorse the reformulated OxyContin as lowering abuse, addiction, and diversion rates.[76]

352. The fourth phase occurred in September 2012. It included a "Semi Structured Payer Interview Guide for Hydrocodone, Oxycontin, Butrans to gather insight re: market access and reimbursement considerations."[77]

353. The fifth phase, occurring in November 2012 included reviewing "Results from Payer Interviews Oxycontin, Butrans, Hydrocodone."[78]

354. The next month, the group started the sixth phase, called "Evidence Generation Plan for OxyContin. Recommendations for a value evidence generation plan to support aspirational value proposition evidence base." OptumInsight relied on this evidence to revise the "Aspirational Value Proposition." One notable change—removing the value proposition that "Abuse of prescription opioids (primary and secondary) has substantial impact on society." The reason behind removal was "Payers value pain management. They perceive tamper resistance and abuse deterrence as societal benefits which they cannot further impact unless all products are tamper resistant." OptumInsight's motivation behind the "Payers value pain management" was financially motivated based on aspirational statement #1 "annual

[76] PPLPC018000697326.

[77] PPLPC020000610710.

[78] PPLP004148372; PPLPC018000742542.

total and direct costs of moderate to severe chronic pain in the US are 2- to 3-fold higher than the economic burden posed by other major conditions such as diabetes, heart disease and obesity.[79]

355. From 2003 to at least 2012, OptumInsight conducted similar studies for other opioid manufacturers. For example, in 2012, OptumInsight did an analysis attempting to show that Suboxone film vs. a tablet formulation was superior to prevent diversion/abuse/misuse.

356. Alongside the studies OptumInsight was producing for Purdue to further legitimize the proliferation of opioids without adequate controls throughout the United States, OptumHealth, a subsidiary of UnitedHealth Care ("UHC"), began an "educational partnership" campaign in the early 2000s to educate nurses and case managers throughout the country on the undertreatment of pain.[80]

357. In 2004, David Rosen, an employee at Purdue, connected his father, Dr. Michael Rosen, a National Medical Director at OptumHealthfrom 1996-2021, with Account Executives at Purdue to begin educating the UHC and client clinical staff on how to effectively manage pain. Dr. Rosen was not only the head medical director at OptumHealth, but UHC's P&T Committee directly reported to him. His son was on the marketing team at Purdue and utilized his connection with his father to connect Purdue with OptumHealth and UHC.

[79] PPLP004148287.

[80] PPLPC021000066876; PPLPC022000059801.

358. In January 2005, Dr. Rosen coordinated with Purdue to present two major Continuing Education Programs to be given to case managers at UHC. The next month, the educational initiatives were implemented.

359. Part of the program targeted nurse practitioners, and included a presentation called "Communication to Enhance Collaboration and Outcomes."[81] The presentation was wholly endorsed and coordinated with Optum's Dr. Michael Rosen.[82] The PowerPoint presentation emphasized the "Possible Adverse Effects of Undertreated Pain" and had speaker notes to quote during the presentation that advocated for increased opioid use and stated "[i]f we continue to provide pain care as it has always been provided, patients will continue to suffer needlessly."[83] The same presentation was given to case managers, then expanded to UHC affiliated groups throughout the country, including to risk managers, telephone triage nurses, and every case manager.

360. In 2006 and 2007, Dr. Rosen and Purdue worked together on multiple programs, including a program called "UHC Educate the Educator."[84]

361. In 2009, Dr. Rosen worked with Purdue to roll out a six month "chronic pain mgmt. program" that would directly link to Purdue's "Partners Against Pain" website.[85] The program would focus on case managers for Optum throughout the

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[81] PPLPC028000120866; PPLPC028000130521.

[82] *See* PPLPC020000038112; PPLPC022000050740; PPLPC022000050741.

[83] PPLPC022000051750.

[84] PPLPC012000105112; PPLPC029000207366.

[85] PPLPC028000245007; PPLPC022000260832; PPLPR001000287899.

country and would focus on Purdue's FACETS modules. The series would be presented by Optum Medical Directors and some Purdue employees. In March 2009, Optum employees reached out to Purdue to facilitate Medical Director Faculty Forum presentations regarding pain. One of the faculty presentations was about how to treat lower back pain with opioids using one of the FACETS topics. Optum distributed the literature for the topic to medical directors. Following this, Purdue held multiple educational seminars with the Medical Directors at Optum to then disseminate this information to hundreds of case managers throughout the country via seminars and literature.

362. In sum, the opioid manufacturers' efforts to disseminate misinformation about opioid addiction, opioid use for chronic pain, and opioids as a first-line therapy inappropriately expanded the opioid market. And since the 1990s, the PBM Defendants collaborated with Purdue to spread this misinformation in an effort to increase opioid utilization and sales. The result of these joint efforts (in Express Scripts own words) was the "opiate explosion: vast increase in prescribing [and] more potent formulations [of opioids]."[86]

D. The PBM Defendants Had Access to Real-Time Data Regarding Drug Utilization Which Gave Them a Unique Vantage Point into the Opioid Epidemic

363. Express Scripts and Optum have had a front row seat to the spread of the opioid epidemic. They have watched as the number of opioids prescribed and dispensed has exploded. They were made aware of opioid epidemic through the vast

[86] ESI_JEFFCOMO_000032900.

amount of data they have had, the knowledge gained through their clients, manufacturers, and other entities in the health care arena, and through clinical evaluations for things such as formulary placement.

1. The PBM Defendants track every prescription claim they process across all the health plans they service which provided them with uniquely granular and comprehensive data.

364. Because of their business model, Express Scripts and Optum have access to an extraordinary amount of data. Express Scripts and Optum can see detailed information on individual prescribers and pharmacies, but can also aggregate that data across manufacturers, patients, pharmacies, and payors. Their visibility into these data is thus both uniquely granular and comprehensive.

365. These data include information such as the volume, nature, dosage, and conditions for which health care providers are prescribing opioids to individual patients and on an aggregate basis; the volume of opioids obtained by individual patients and by geography; the pharmacies at which opioids were dispensed and the volume of opioids dispensed by geographic area, among other data. Express Scripts and Optum also had data from their own mail order pharmacies.

366. For the past two decades, Express Scripts has processed 8 to 10 million prescription claims per day—1.4 billion claims per year—for its members with hundreds of data points for each transaction. At all times since the 1990s, Express Scripts has had as much—if not more—detailed claims data on opioid utilization and prescribing than any other entity in the pharmaceutical industry.

367. Express Scripts not only collected prescription data, but also analyzed it to track utilization patterns. Since 1997 Express Scripts has compiled in-depth drug utilization analyses of its own claims data from millions of Express Scripts' members across the country in its Drug Trend Reports. Starting in at least 1999, Express Scripts Drug Trend reports reflected both Express Scripts' knowledge of increasing OxyContin and opioid utilization, as well as its understanding of the dangers of these drugs.

368. Express Scripts' ability to monitor and analyze opioid prescription data is exemplified by its 2014 "A Nation in Pain" report focusing on the opioid epidemic. The report reviewed 36 million pharmacy claims from 2009 to 2013, which illustrated the widespread opioid epidemic. In the report, ESI demonstrated its ability to identify opioid use trends by geography, age, and gender, as well as by the prevalence of doctor and pharmacy shopping and drug cocktail use.

369. Optum (and/or its predecessors) have had access to data for its 66 million UHC and OptumRx covered lives for the duration of the relevant time period as well, processing 3.8 million prescription claims per day, or 1.4 billion a year. Before 2011, Optum had access to claims for over 75 million individuals nationwide. Since its inception, Optum has been able to track how many opioids its millions of members were receiving, including the quantity of pills, the dosing strengths, the combination of drugs being dispensed, and the travel distance of members to acquire prescription opioids. Additionally, Optum has access to clinical information for millions of

patients, which includes clinical files and over 4.5 billion text notes from a member's clinical records.

370. In a presentation touting the effectiveness of Optum's opioid management program, Optum's Senior Vice President of Clinical Engagement described the power that Optum has to not only track data, but to use it to stop inappropriate opioid utilization at the pharmacy counter:

> "I have billions of claims, literally billions of claims. Every claim that we go through goes through an algorithm. This is all happening in realtime at the pharmacy. When you go to the pharmacy, in microseconds, I know if my patients are on a concurrent benzo. I know what the dose is. I know what the day's supply is. I know what other drugs they're taking, and I can have realtime [point of sale] edits going through making sure everything is happening appropriately."[87]

371. Similarly, Optum has touted its ability to use "near-real-time data feeds to integrate medical claims data into our intelligent claims engine," and boasts that "[o]ur data capabilities are structured in order to flag these individuals using both our own pharmacy claims data plus medical claims data."[88] Furthermore, OptumRx claims "[w]hen it comes to identifying at-risk patients, we get maximum leverage out of our claims-paying role as a PBM. In this capacity, we have direct insight into which patients are getting which drugs." Before 2007, Prescription Solutions (OptumRx's predecessor) had the ability to review every claim submitted by its members and "look for problem patterns and intervene with prescribers closer to the point of a member's care," including being able to identify both doctor shopping and pharmacy shopping

[87] Beshara Dep. 61:9-62:3 (Sept. 12, 2023).

[88] OPTUMRX_JEFFCO_0000004463 (8/25/20).

by patients as well as other red flags such as early refills or suspicious drug combinations.[89]

372. OptumRx has described its "comprehensive retrospective drug utilization review" ("RDUR") as "specifically designed to look for problem patterns and intervene with prescribers closer to the point of a member's care," including being able to identify both doctor shopping and pharmacy shopping by patients as well as other red flags such as early refills or suspicious drug combinations.[90] Furthermore, OptumRx claims:

> When it comes to identifying at-risk patients, we get maximum leverage out of our claims-paying role as a PBM. In this capacity, we have direct insight into which patients are getting which drugs. This insight feeds our RDUR capability.
>
> The RDUR clinical opportunities directly contribute preventing progression to chronic use. For example, retrospective data helps identify "shoppers," those that are using multiple physicians, pharmacies, and/or multiple prescriptions. This is key, because when patients are using multiple prescriptions it is not uncommon to see dose escalation over time, putting them at higher risk for overdose.
>
> The system is also looking for other patterns of high risk behavior, such as early refills, or those who are using dangerous combinations of products.[91]

373. Optum's ability to control drug utilization was best stated by Dr. David Calabrese, Optum's Chief Clinical Officer, "we drive the ship in terms of how their drugs get used, not [the opioid manufacturers]."[92]

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[89] *Id.*, at p. 5.

[90] *Id.*, at p. 5.

[91] *Id.*

[92] OPTUMRX_JEFFCO_0000360074.

374. Because of all of data they had, the PBM Defendants were aware that the volume of opioids being prescribed in the United States, and in the Plaintiffs' jurisdiction, far exceeded an amount that could possibly be justified as medically necessary or appropriate. They knew that opioids were being overprescribed and used inappropriately, and that the Plaintiffs' communities were being flooded with an oversupply of these dangerous drugs.

375. To make matters worse, rather than use their data to stop the public health crisis that they were watching unfold, since at least 1997, the PBM Defendants sold their detailed claims data, as well as their clients' formulary and health plan information, to Purdue and other opioid manufacturers. The opioid manufacturers then used this data to gain insight into the pharmacies and health care providers who were dispensing and prescribing their opioids (as well as their competitor's products) *and more importantly* those pharmacies and prescribers who were *not* prescribing and dispensing their products. This allowed sales representatives of Purdue and the other opioid manufacturers to have laser precision targeting high prescribers and pharmacies in order to aggressively push opioids onto the market.

376. For as long as they have been PBMs, Express Scripts and Optum have received, compiled, and analyzed massive amounts of prescription claims data demonstrating that opioids were being over-utilized, abused, and diverted. Indeed, these PBMs had more data on and awareness of the opioid epidemic unfolding than any other entity in the pharmaceutical industry. They knew or certainly should have known for decades that opioids were causing a public health crisis.

2. The PBM Defendants had knowledge about the opioid epidemic and about abuse and diversion.

377. According to the CDC, the rise in opioid overdose deaths can be outlined in three distinct waves. As the CDC explains: "The first wave began with increased prescribing of opioids in the 1990s, with overdose deaths involving prescription opioids (natural and semi-synthetic opioids and methadone) increasing since at least 1993. The second wave began in 2010, with rapid increases in overdose deaths involving heroin. The third wave began in 2013, with significant increases in overdose deaths involving synthetic opioids, particularly those involving illicitly manufactured fentanyl."[93]

378. Very recently, as of September 2023, the United States has entered the Fourth Wave of the Opioid Epidemic. A study[94] released by the Center for Social Medicine and Humanities, University of California, Los Angeles, California, USA, found that "recently, scholars have argued that the 'fourth wave' of the US overdose crisis has begun, in recognition of rapidly rising polysubstance overdose deaths involving illicitly manufactured fentanyl, with stimulants playing a key role. By 2021, methamphetamine and cocaine were the only leading co-involved substances as depicted below. This represents current 2021 trends, a culmination of a long road of crisis level addiction beginning with *prescription opioid abuse***.**

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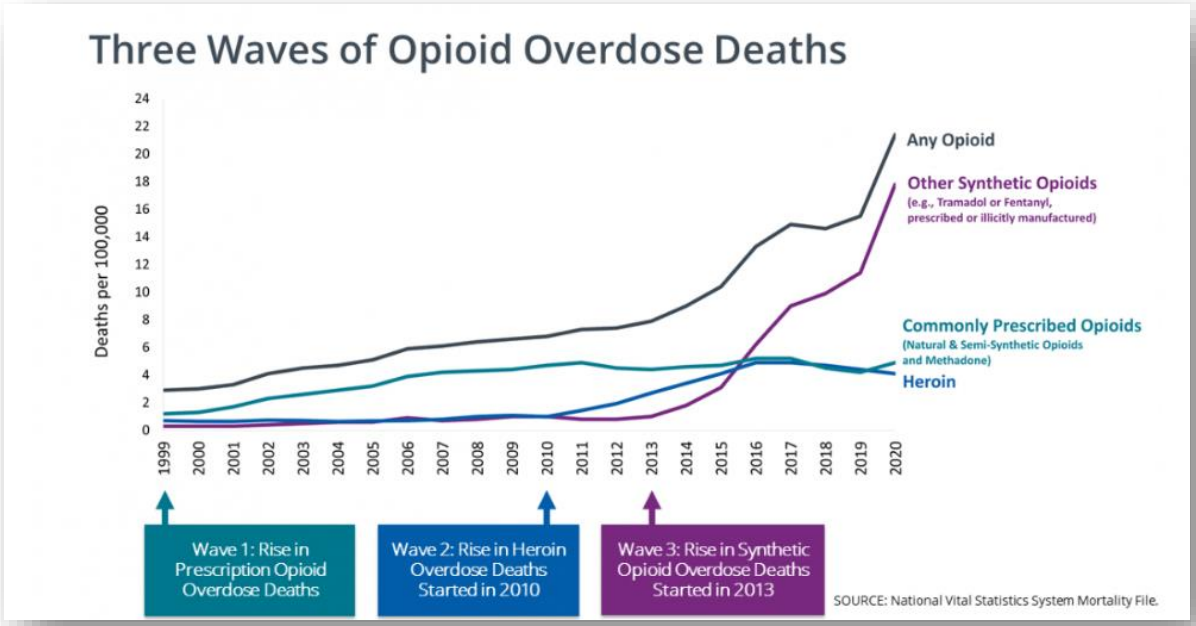
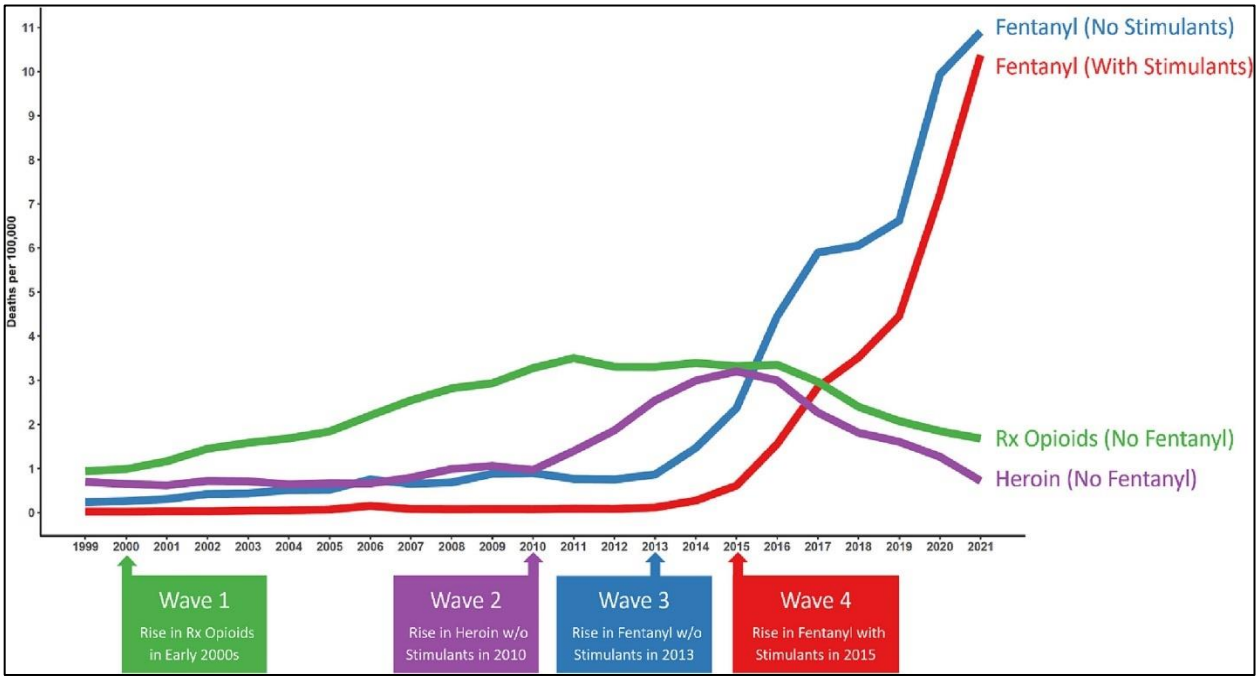
[93] *Id.*

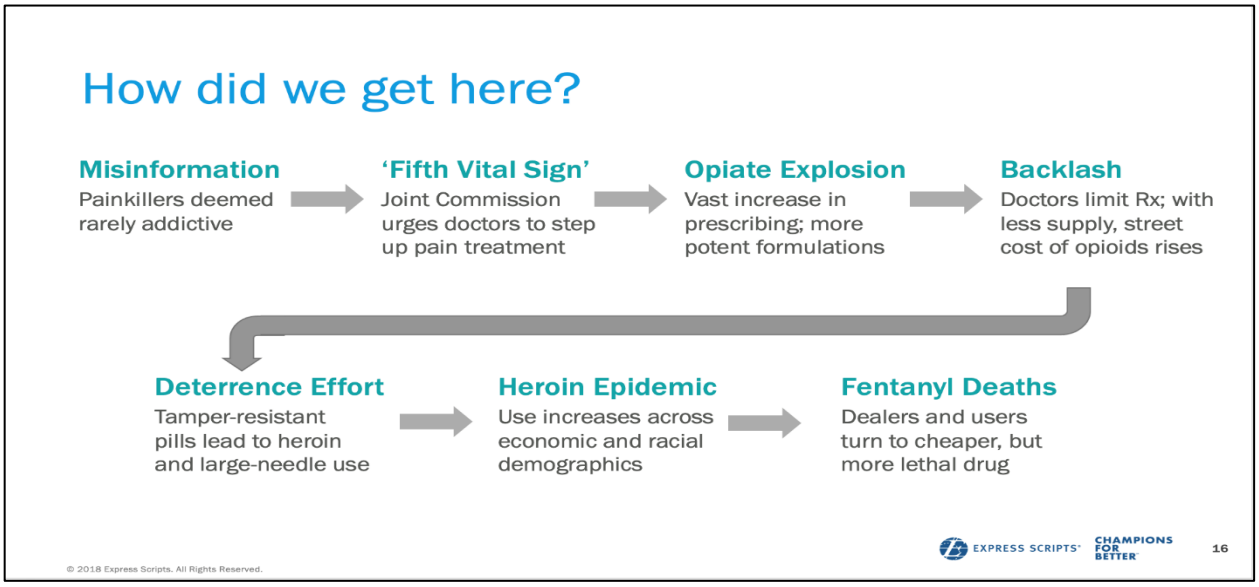
[94] Friedman, J, Shover, CL, Charting the fourth wave: Geographic, temporal, race/ethnicity and demographic trends in polysubstance fentanyl overdose deaths in the United States, 2010–2021, 118 ADDICTION 12 (Dec. 2023), https://doi.org/10.1111/add.16318.



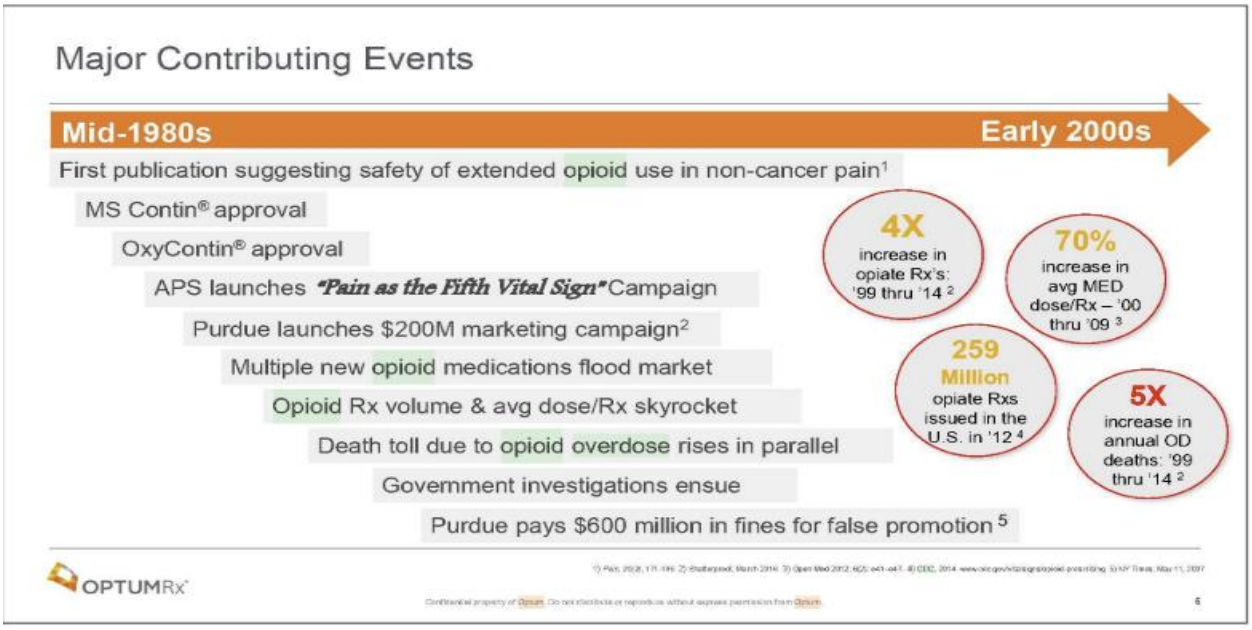
379. The following chart, depicting "Geographic, temporal, race/ethnicity and demographic trends in polysubstance fentanyl overdose deaths in the United States, 2010–2021" shows the four waves of the epidemic:



380. Express Scripts own marketing material explicitly recognized this evolution in the national opioid crisis:[95]



381. Likewise, Optum's promotional material also acknowledged these progressive stages of the opioid epidemic:[96]



95 ESI_JEFFCOMO_000032900.

96 OPTUMRX_JEFFCO_0000341787.

382. Long before the second wave of the crisis started in 2010, both Express Scripts and Optum knew that opioid abuse and misuse posed serious problems.

383. The PBM Defendants knew that opioids were addictive and carried a significant risk of serious injury or death, and they have known this for at least the past 20 years.

384. For example, both Medco and Prescription Solutions informed Purdue that they had concerns about the potential for abuse in OxyContin right out of the gate in 1997. A few years later, in early 2001, an executive of Optum's parent company, UHG, wrote to Purdue to discuss the "whole OxyContin overuse issue . . . which has been brought about by the 'heightened marketing skills of Purdue." The email continued, "I believe Purdue has acted irresponsibly in over-promoting the use of oxycodone . . . the activity has resulted in the overuse of morphine, an increase in the abuse of this narcotic, unnecessary and significant increases in pharmacy trend, and most importantly, an increase in patient morbidity and mortality."[97] In other words, Optum/UHG recognized that OxyContin was being overused and killing people in increasing numbers over two decades ago.

385. Similarly, starting in at least the early 2000s, certain Express Scripts and Medco clients also began to express concern to them about abuse and diversion issues related to OxyContin. Upon hearing from their clients, Express Scripts and Medco would often reach out to Purdue directly seeking help to quash these concerns.

[97] PKY181977016.

Purdue often worked with the PBM Defendants by providing research and "educational" materials downplaying the risks associated with opioid use.

386. For example, in 2002, internal Purdue emails describe a call with Medco regarding clients who "had concerns about tablet restrictions and proper utilization of OxyContin."[98] Medco informed Purdue that "an overview of the abuse and diversion issue surrounding OxyContin would be helpful for [Medco] to respond to their customers questions/concerns."[99]

387. In 2003, Medco's largest client, UHC, expressed concerns that "there were patients taking 960-1000 tabs of OxyContin per month" and stated that it wanted to take action "to reduce the abuse and diversion issues." Following this, Medco and Purdue worked together to compile research and data to provide to this client to alleviate these concerns.

388. Also in 2003, an Express Scripts employee gave a presentation at a 2003 conference in which that employee, while discussing OxyContin, stated, "This is a narcotic. All narcotics are addictive. In addition, this is a controlled release narcotic, so when someone would crush it up and either ingest it or inject it there was a potential for serious injury or even death."[100] This same Express Scripts employee also indicated that because patients were becoming tolerant, chronic use of opioids was occurring and patients were taking increasingly higher doses over time

[98] PPLPC029000063491.

[99] E01_00004716.

[100] *See* PPLPC012000061345, 13486 (6/5/03) (family).

(sometimes referred to as "dose-creep" or "dose-creeping").[101] Following a study of opioid use in a private plan that revealed this pattern, Express Scripts conducted an internal study and "found that similar patterns were occurring . . . across ESI's book of business."[102]

389. The PBM Defendants also knew or had reason to know that opioids were being improperly marketed. They were aware, for example, that the price of at least some opioids (including OxyContin) increased as dosage increased. And when describing this dose-creeping phenomenon during the 2003 conference, an Express Scripts employee suggested that this phenomenon is not merely attributable to tolerance from chronic use—he said dose-creeping "may be reflective of detailing for this drug."[103] Indeed, a Purdue employee who attended this conference said in an email to other Purdue personnel that "[Express Scripts] is looking at the detailing of the drug. [Express Scripts] implied that there may be improper detailing by the manufacturer."[104]

390. The PBM Defendants also knew that opioids were being improperly marketed because, in 2007, Purdue pleaded guilty to criminal misbranding of OxyContin. The plea agreement identified specific representations that Purdue acknowledged were false. The PBM Defendants knew that these same misrepresentations were still being used by Purdue and others in the marketing of

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[101] *Id.*

[102] *Id.*

[103] *Id.*

[104] *Id.*

prescription opioids. Yet they failed to use their standard formulary and UM offering to counteract the effects of this fraudulent marketing.

391. In 2006, Express Scripts executives again recognized the abuse risk opiates posed. But Express Scripts was reluctant to implement more robust monitoring for fear of customer blowback and loss of prescription volume:[105]

From: Behm, Andrew (BLM)
Sent: Monday, August 14, 2006 2:08 PM
To: Gross, Amy (BLM); Colby, Andrew J. (STL)
Subject: RE: Retro DUR Addictive Substances question

No Stadol. We previously targeted all controlled substances plus Tramadol, Soma, and combos of those products.

When we enhanced the targeting, CPMs were only really interested in the opiates from an abuse perspective. I suppose we could revisit the targeting --- especially if you're aware of any new feedback --- but that will definitely impact the number of letters and volume.

392. As early as 2008, Express Scripts acknowledged the acute diversion risk with opioids. For example, Express Scripts employee Adam Kautzner (now its President) noted the "improved street value" of brand name narcotics:[106]

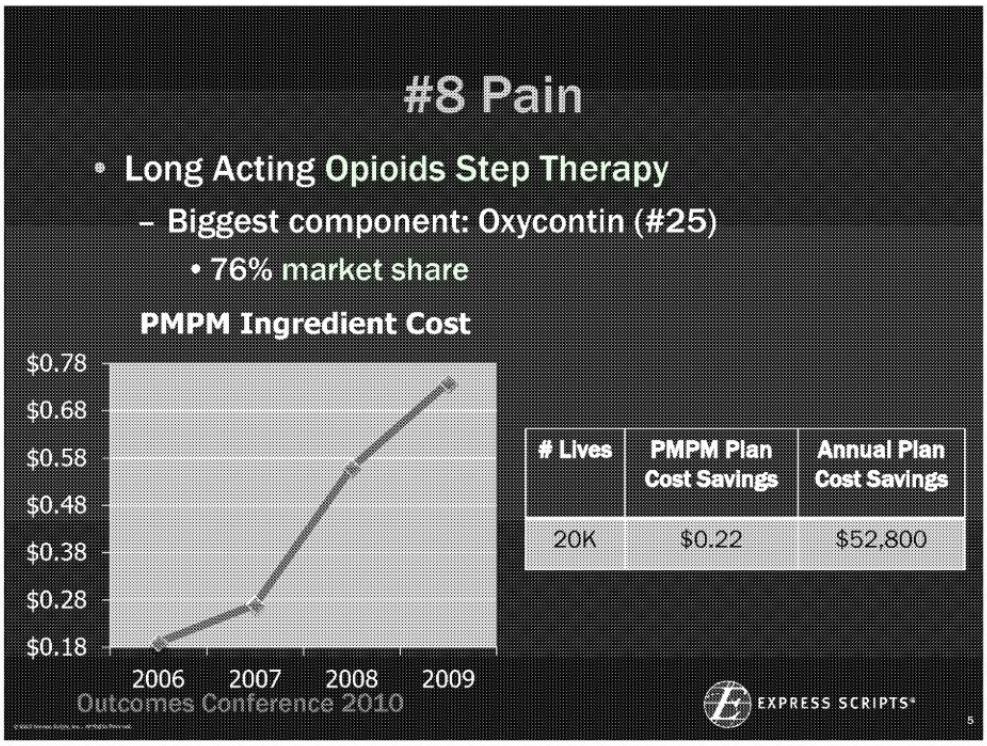
From: Kautzner, Adam W. (EHQ)
Sent: Tuesday, November 04, 2008 11:32 AM
To: Gross, Amy (BLM); Martin, Jason (STL)
Cc: Boike, Jackie L. (BLM)
Subject: RE: file on temp transfer drive

I was afraid this was going to be your response!
Brand name narcotics may especially be interesting with their improved street value.
I will dig in my email archives for requests but haven't had many lately. Especially for QLLs.

[105] ESI_JEFFCOMO_000260226 (8/14/06).

[106] ESI_JEFFCOMO_000273681 (11/4/08).

393. The following slide was included in a client-facing presentation discussing the 2008 Express Scripts Drug Trend Report. The slide included speaker notes acknowledging Express Scripts' own awareness that in 2008 it needed to do something about OxyContin abuse: "We all know the abuse potential for [Oxycontin] and we knew that a solution needed to be offered to all of you here if you wanted to address it:"[107]



394. In 2009, Express Scripts received an email from a client stating, "Houston, we have a problem, and its name is Oxycontin."[108] That same year another

[107] ESI_JEFFCOMO_000278190; ESI_JEFFCOMO_000278192.

[108] Gross Dep. 55-56, Ex. 4; *see also* Gross Dep. 74 (discussing exhibit in same time period where ESI clinical personnel observed that "there has been quite a bit of client buzz around increasing Oxycontin use")).

large client reached out to Express Scripts regarding its desire to put into place an "aggressive PA policy" on opioids to combat "rampant abuse and inappropriate" opioid use.[109]

395. Another example occurred in 2011, when Express Scripts Vice President of Clinical Evaluation & Policy wrote to the chair of one of Express Scripts formulary committees, stating:

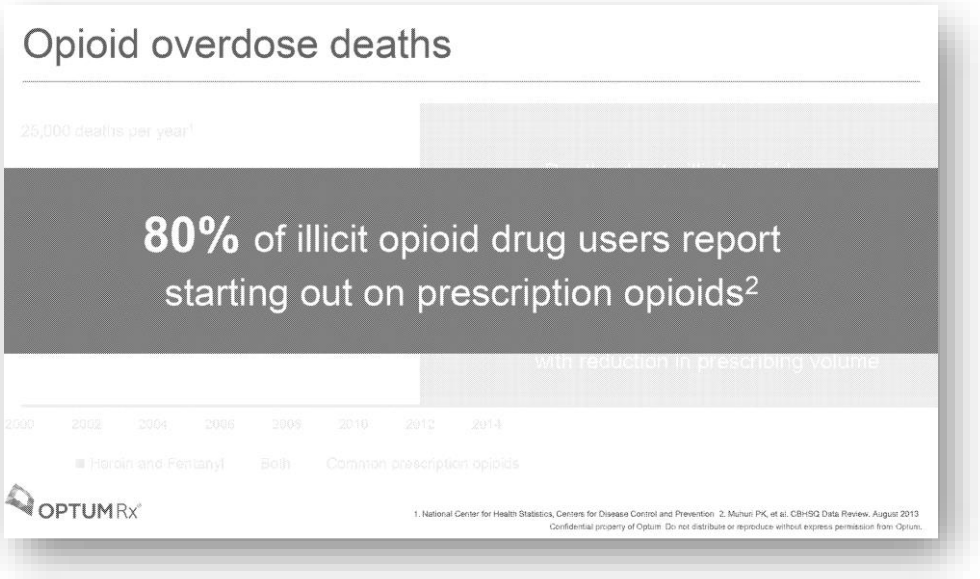
> I think the overutilization of opiates continue to be a significant problem. From what I've heard, there are thoughts out there that the opiates are being greatly over-utilized by patients with chronic non-cancer pain . . . MDs should be pushing for more non-opiate pharmacotherapies and non-pharmacologic options.[110]

396. Not only that, but the PBM Defendants were well aware for years that as many as 80% of users of illicit opioids started out using a prescription opioid. Below is a slide from a presentation by OptumRx Chief Pharmacy Officer Calabrese, quoting from a 2014 CDC study in this regard:[111]

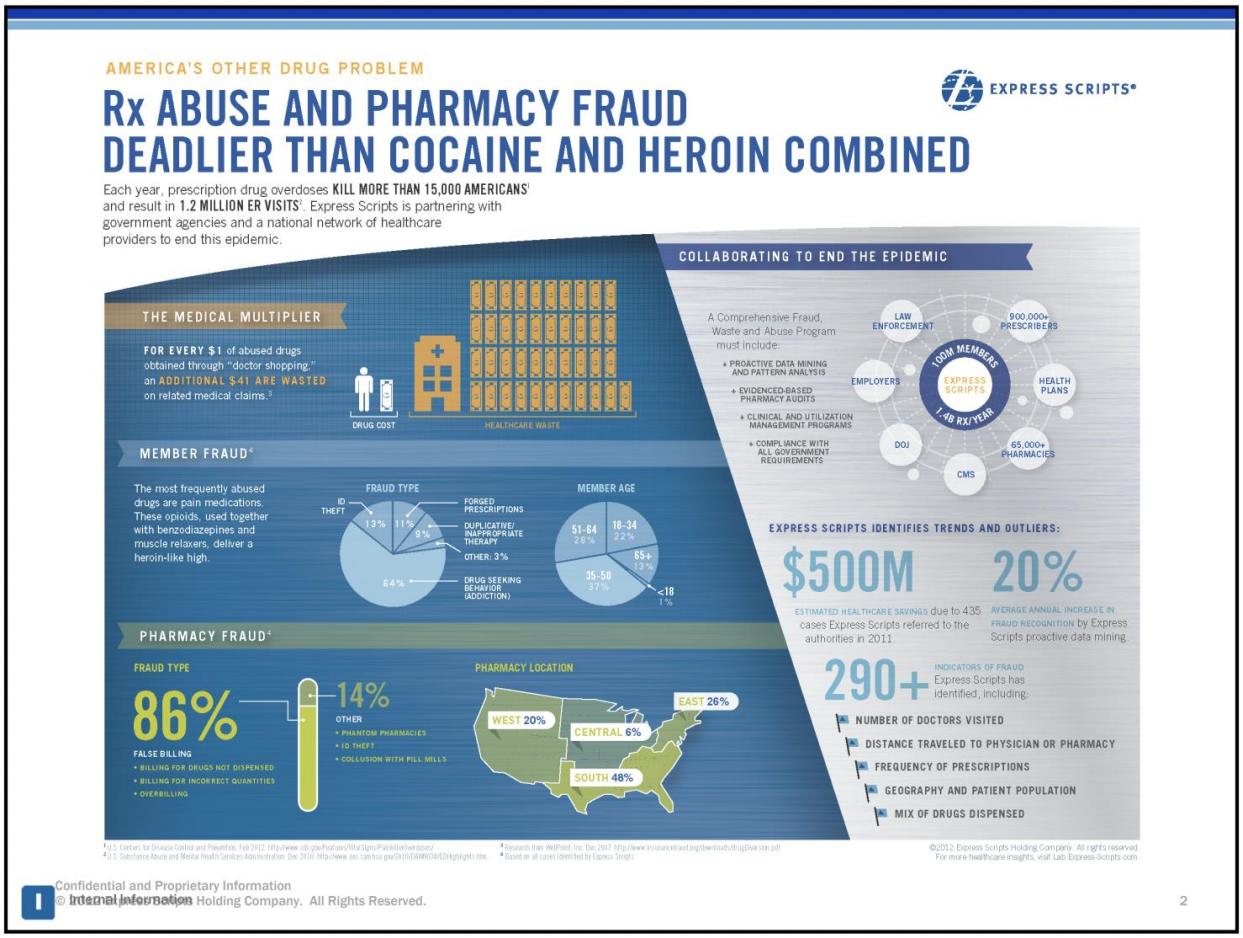
[109] ESI_JEFFCOMO_000259907.

[110] ESI_JEFFCOMO_000299137.

[111] OPTUMRX_JEFFCO_0000374488 (5/8/18).



397. In 2013 Express Scripts put together the following client-facing marketing poster utilizing its own data, as well as outside sources, that not only recognized that opioid abuse was "deadlier than cocaine and heroin combined" but also recognized the pivotal role that Express Scripts plays in "collaborating to end the epidemic":



398. Express Scripts' 2014 report, "A Nation in Pain," concluded, among other things, that "[p]rescription rates for opioids increased dramatically in the past two decades . . ." and that "[o]pioid abuse is an epidemic in the U.S."[112] "A Nation in Pain" also referenced a separate ESI study that found that 40% of opioid prescriptions filled by members with employer-sponsored drug coverage between 2011 and 2012 were written by only 5% of prescribers.[113]

[112] "A Nation in Pain: Focusing on U.S. Opioid Trends for Treatment of Short-Term and Longer-Term Pain, An Express Scripts Report," (Dec. 2014), https://d11tr245s7jfj6.cloudfront.net/2019-08/Opioid%20Report_0.pdf.

[113] ESI_JEFFCOMO_000003092 (12/9/14).

399. The PBM Defendants knew about the epidemic not only from their own data, but from other sources as well. One of these sources was almost surely their own P&T committees. These committees have historically been concerned with "the documented safety and efficacy of new drug formulations."[114] P&T committees are typically "comprised of physicians, pharmacists, and other clinicians" that meet regularly to keep up with the fast pace of pharmaceutical innovation.[115] Express Scripts, for example, describes its P&T Committee as "a panel of independent physicians and pharmacists in active clinical practice, representing a variety of specialties and practice settings and typically with major academic affiliations."[116]

400. The University of Wisconsin-Madison Division of Pharmacy Professional Development lists, among its "5 Best Practices for P&T Committee Members," the need for committee members to "be informed," "be objective," and "emphasize patient-focused outcomes."[117] In particular, to stay informed, "[t]hey should regularly seek out information from reputable sources, including peer-reviewed journals, industry thought-leaders and the FDA."[118] With respect to being

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[114] Zhixiao Wang et al., "Cost-Effectiveness Analysis and the Formulary Decision-Making Process," *Journal of Managed Care Pharmacy,* Vol. 10, no. 1, pp 48–59 at p. 48 (Jan./Feb. 2004).

[115] Peri Iz, "Study of Pharmaceutical Benefit Management," PricewaterhouseCoopers HCFA Contract No. 500-97-0399/0097, p. 79 (June 2001).

[116] Express Scripts Holding Company, 2017 SEC Form 10-K, at p. 5 (Dec. 31, 2017) https://www.sec.gov/Archives/edgar/data/1532063/000153206318000004/esrx-12312017x10k.htm.

[117] UW-Madison School of Pharmacy, Division of Pharmacy Professional Development, *5 Best Practices for P&T Committee Members*, (Sep. 25, 2023), https://ce.pharmacy.wisc.edu/blog/5-best-practices-for-pt-committee-members/.

[118] *Id*.

objective, the Division notes that "[f]ormulary decisions are objective and evidence-based."[119] When discussing the focus on patient outcomes, P&T committee members "should be focused on the quality, efficacy, and safety of the treatment patients receive."[120]

401. Given this responsibility to stay informed, P&T committee members knew or should have known of the nationally available information regarding the risks of opioids. And through these P&T committees, the PBM Defendants knew or should have known that information throughout the relevant time period.

3. The PBM Defendants Failed to Timely Undertake Actions to Address the Opioid Epidemic that They Helped Create.

402. The PBM Defendants not only had knowledge of the dangers of opioids, they had the ability and the opportunity to rein in opioid access, but chose not to.

403. As early as 2007, Prescription Solutions, OptumRx's predecessor, identified patients engaging in doctor and pharmacy shopping for opioid analgesics as part of its Narcotic DUR program. However, the scope of the Narcotic DUR was extremely narrow: to be identified by the program, a patient had to see four or more prescribers for the exact same opioid analgesic, or fill prescriptions for the exact same opioid analgesic at three or more pharmacies, within a three-month period. And even when patients were identified under these limited criteria, the action taken was minimal. The prescribers involved received a fax or mailing with the patient drug utilization information and materials on "appropriate opioid use"—based on

[119] *Id.*

[120] *Id.*

guidelines by the American Pain Society and the Federation of State Medical Boards, pro-opioid front groups working closely with the opioid manufacturers. These mailings, unsurprisingly, did little to change prescribing patterns; if a prescriber chose to respond, he or she could simply state that the medication use was appropriate. And if the prescriber responded that further monitoring for that patient was not needed, Prescription Solutions would exclude that patient from any subsequent reports. The program did nothing to limit the quantity of opioids the prescribers could provide, nor did it identify prescriber-level red flags, such as writing the same controlled substance prescription repeatedly or writing a high ratio of controlled substance prescriptions compared to other drugs.

404. In a 2013 email, an OptumInsight Life Sciences consultant forwarded an article to opioid manufacturer Endo indicating that CVS was cutting opioid access for "risky" prescribers and that OptumInsight could do the same: "Within our data, we can track the physicians, their # of prescriptions within the Optum database, their patients comorbidities and conditions (e.g. do their patients have pain issues?) . . . We can also track the pharmacies as well."[121]

405. In 2013, Catamaran, a PBM that subsequently became part of Optum, promoted its ability to identify "current as well as future at-risk patients and drive interventions in our clinical programming" based on a "dynamic rules engine that

[121] ENDO-OPIOID_MDL-02875114 (8/26/13).

continuously scans patient data." Catamaran claimed it could identify these risks "in real time" based on just 30 days of prescription data.[122]

a. The PBM Defendants chose not to use their claims data and their formulary, and UM offerings to address overprescribing, abuse, and diversion

406. Claims data available to the PBM Defendants gave them the ability to identify opioid abuse and fraud. Having individually identifiable information for patients, physicians, and retail pharmacies allowed the PBM Defendants to analyze opioid utilization, patterns, and abuse. Yet despite having an array of available, commonly used tools to detect physician overprescribing and manage patient drug utilization, the PBM Defendants failed to timely implement opioid limits that would have drastically reduced the inappropriate prescribing and dispensing of opioids, and failed to reveal what they knew from the data they collected and analyzed so informed decisions could be made about ongoing dispensing practices and system-wide abuses. Moreover, the PBM Defendants were at the same time contracting with opioid manufacturers for payments of rebates and fees based on utilization, without restriction, of opioids.

407. The PBM Defendants have been on notice for decades that they needed to and had the ability to address the overutilization of prescription opioids, which was contributing significantly to the growing opioid crisis.

[122] OPTUMRX_JEFFCO_0000026040 (1/24/13).

408. For instance, *Express Scripts' own studies dating back to at least 2002* demonstrated the effectiveness that UM tools such as prior authorizations had at decreasing inappropriate opioid overutilization.

409. In 2002, Express Scripts researchers conducted a study to "examine the clinical and economic outcomes associated with a prior authorization (PA) requirement for OxyContin." The results of the study were: "post (PA) implementation PMPM claims and expenditures for OxyContin decreased significantly without an increase in PMPM trend. The PMPM trend in claims for other C-2 narcotics slowed. Results indicated that those who obtained PA approval were more likely to have had a pain-related diagnosis than those who did not attempt PA approval but there was no difference in pain-related health services use between the groups after PA implementation." In other words, Express Scripts' own research conducted in 2002 demonstrated that prior authorization significantly decreased inappropriate OxyContin utilization.

410. In response to this study, Purdue executives expressed concern that the study may decrease OxyContin utilization: "The emphasis [that the study] placed on statements about areas of tolerance, safety, abuse and detailing of the product may have left the impression that other ESI Medicaid and commercial clients should consider implementation of a similar restriction on OxyContin."[123]

411. That same year, in 2003, describing how opioids were dispensed to Medicaid patients in the State of Georgia, one ESI employee noted how the

[123] Henderson Dep. Ex. 18; Henderson Dep. Ex. 19.

deployment of a prior authorization process significantly curtailed OxyContin use in that state:

> Now for this particular program there was a special kind of PA [prior authorization] [for opioids] and it included quantity level limits. So what was happening in this PA was that a patient would call-in for the approval and at that time depending on their indication for short-term pain such as a fracture or long-term pain such as cancer, they would get the length of the amount of refills they get. So for the short-term they would be allotted two one-month refills for the drug. For the long-term pain they would get up to six one-month refills for the drug. So . . . we looked at the outcomes and in this case we examined pain related emergency room visits. Now understandably this is not the best way to assess a pain outcome, but we had limited data, we had to do a retrospective analysis. If we had been able to do it prospectively we would have looked at things such as quality of life and activities of daily living.[124]

412. The result of this PA program was that, "For this client, this plan, Oxycontin went from ranked number seven to number 14 in drugs spent after the PA implementation."[125] Importantly, Express Scripts "found that [these] patients who did not receive the Oxycontin did not have a greater use of medical services[,] so there was not an unintended medical consequence from this program."[126] And not only did Express Scripts "think this [Georgia] program worked," but it also declared that "this isn't just exclusive to [Express Scripts], but any PBM should be doing these things."[127] Unfortunately, it was not until fourteen years later that Express Scripts started to push clients to implement systemic opioid management tools.

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[124] PPLPC012000061348 (6/4/03).

[125] *Id.*

[126] *Id.*

[127] *Id.*

413. In 2006, Express Scripts again conducted a study on its Medicaid population that showed the effectiveness of PA's on reducing Oxycontin utilization. Specifically, a state-run Medicaid program had been concerned about the chronic use and potential abuse of OxyContin™, a Class 2 narcotic. Express Scripts also noted that "media and legislators had raised questions regarding potential abuse of OxyContin. Express Scripts implemented a prior authorization to "limit the medication to only those patients with a demonstrated medical need" and incorporated a quantity limit. At the end of a year of this program, Express Scripts found that "patients who requested a prior authorization were more likely to have a pain-related diagnosis than those members who did not request a prior authorization after being denied at the pharmacy." Express Scripts also concluded that the "prior authorization program addressed this Medicaid program's goal of fostering appropriate pain management while not increasing the use of emergency services for pain."[128]

414. Despite knowing for decades that prior authorizations were a best practice for preventing opioid overutilization and abuse, Express Scripts failed to create or offer a standard prior authorization protocol on opioids to its clients until 2017—after the Senate had contacted Express Scripts (twice) regarding its role in the opioid epidemic.

415. To make matters worse, Express Scripts had considered implementing a prior authorization on opioids as early as 2007. Internal Express Scripts documents

[128] ESI_JEFFCOMO_000306081.

reveal that Express Scripts had received "requests in 2007 for [point of sale] programs for inappropriate narcotic utilization . . . [because] a more robust standard program covering all narcotics was desired."[129] Express Scripts elected not to pursue this program.

416. Indeed, when the FDA in 2013 removed the indication for use of long-acting narcotics to treat moderate pain, Express Scripts admitted, "we don't really have a standard OxyContin PA program. Our current UM strategies are more focused on driving preferred products and managing quantities."[130]

417. Prior to 2017, whenever Express Scripts was questioned by federal or state governments or its own clients on what it was doing to combat opioid abuse, it pointed to its step therapy policy on long-acting opioids (LAO). This policy required a patient to try a generic opioid before the patient could be dispensed a brand opioid.

418. However, Express Scripts knew its LAO step policy was not created to address opioid overutilization or abuse. Rather, it was merely a cost containment and stockpiling/waste measure. In fact, in 2011, Express Scripts Vice President of Clinical Evaluation & Policy, Andrew Behm, wrote to Express Scripts Clinical Director Amy Gross asking whether the following statement in the draft Drug Trend Report was true: "Possible abuse continues to concern plan sponsors. In 2010, Express Scripts initiated a long-acting opioid strategy designed to ensure that published pain-treatment guidelines are followed." Amy Gross responded:

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[129] ESI_JEFFCOMO_000273099; ESI_JEFFCOMO_000273100.

[130] ESI_JEFFCOMO_000169781 (9/11/13).

> What??? The [long acting opioid step therapy policy] has nothing to do with pain treatment guidelines. It is just generic before brand. Then we updated the OxyContin [Drug Quantity Management] to include the other long-acting meds. But again not to ensure published treatment guidelines were follow. I HATE this sentence . . .The [Step Therapy] and [Drug Quantity Management] are in place for cost-containment (generic before brand) and stockpiling/waste.[131]

419. On its face, it is clear Express Scripts' long-acting step therapy policy was never intended to limit opioid overutilization or abuse. Generic versions of the long-acting opioids are just as addictive as the brand versions. Stepping from a generic version to a brand did not promote effective use of opioids; rather it opened the gates to the use of generic long-acting opioid given that for the most part generic versions of these drugs were unrestricted, Tier 1 status on Express Scripts' standard formularies.

420. Express Scripts could have created a policy where the Step 1 drug for certain patients was a non-opiate product. Indeed, the same year that Express Scripts implemented its LAO step policy, Express Scripts Vice President of Clinical Evaluation & Policy, Andrew Behm acknowledged that "overutilization of opiates continue to be significant problem" and recognized that "non-opiate pharmacotherapies" should be promoted.[132] Yet, Express Scripts failed to offer a non-opiate step and opted instead to create a policy that substituted an opioid for another opioid.

[131] Gross Dep. Ex. 4.

[132] ESI_JEFFCOMO_000299137.

421. Express Scripts also failed to implement this policy during crucial years when the opioid epidemic was taking root as brand opioids (such as when OxyContin which was released in 1996) were expanding the pain treatment market and were being heavily abused and diverted. Had Express Scripts implemented a step therapy policy in the early 2000s that shifted utilization from brand opioids to non-opioid pain treatments it could have had a significant impact on the opioid epidemic. But Express Scripts failed to do so.

422. By the time that Express Scripts enacted its long-acting opioid step policy, its financial incentives with respect to opioids had shifted and Express Scripts was making more money on generic opioids.

423. Therefore, while Express Scripts long-acting opioid policy did nothing to address the opioid epidemic, it did shift utilization from addictive brand opioids to equally addictive generic opioids that were more profitable for Express Scripts.

424. To make matters worse, prior to 2017, Express Scripts knew that the programs it ostensibly had in place to address opioid overutilization were failing. For example, a 2015 email from the head of Express Scripts' eFWA program to Express Scripts Vice President of Clinical Evaluation & Policy stated:

> [Express Scripts Fraud, Waste, and Abuse Department] have been seeing way to many egregious drug seeking activity over the years. So much so that it is hard to defend how our systems would allow 68 control scripts by 47 physicians, and 28 pharmacies in a year for one patient. *This is one of many that we use as examples*. My thought is to try to fix this issue as well as the patient safety concern on the front end. Who could I work with around the control substance logic at POS edit? There has to be something to stop this proactively.[133] (Emphasis added).

[133] Nader Dep. Ex. 10.

425. In another example, an Express Scripts fraud, waste and abuse investigation using its data mining and analytics tools for its client [redacted] benefit plan found that one plan member filled 49 opioid prescriptions from 14 prescribers at 6 pharmacy locations in 14 months' time. Another [redacted] member had filled 36 opioid prescriptions in just one year's time, including some 1,898 dosage units (749 days' worth) in just one year. Yet another [redacted] member filled 29 opioid prescriptions in just 5 months' time. Despite these clear examples of gross over-dispensing, Express Scripts refused to change course and implement programs that it knew would have reduced inappropriate opioid utilization such as prior authorizations.

426. Had Express Scripts created and offered a robust prior authorization program on opioids in 2007 it likely would have resulted in tens (if not hundreds) of millions of fewer opioids being dispensed throughout the country, including in Plaintiff's Community.

427. For years, Optum also expressed concerns regarding implementing prior authorizations and offering other Utilization Management protocols because of lost profits.

428. For example, OptumRx would frequently put PAs on opioid products that did not offer high enough rebates, and thus use the PA to steer use to "preferred" opioids—typically OxyContin products.

429. The best example of this occurred in 2013, OptumRx created a "pay to avoid PA" program on long-acting opioids. This was not a clinical PA; instead, it was

a threat to extract higher rebates from the opioid manufacturers. The strategy was simple, make the opioid manufacturers "Pay to avoid a PA."[134] The PA only required documentation of failure of multiple other preferred opioids.[135]

430. Clinically appropriate prior authorizations were not placed on Optum's highest selling long-acting Opioids for OptumRx until January 1, 2018, because the profitability of long-acting opioids would necessitate that *any* edit would need to be "thoroughly reviewed."[136] This required OptumRx to renegotiate all its current rebate agreements with opioid manufacturers.

431. OptumRx did not offer a standard prior authorization program targeting short-acting opioids until the launch of its Opioid Risk Management Program in late 2017, despite Optum being aware that opioid abuse was driven primarily by short acting generic opioids.

432. Beyond prior authorizations, by no later than 2011, the PBM Defendants had been put on notice by the Centers for Medicare and Medicaid Services ("CMS") that all actors involved in delivery of healthcare in the United States needed to take steps to address the overutilization of prescription opioids, which was contributing significantly to the growing opioid crisis.

433. In September 2011, CMS sent a memorandum to "All Part D Sponsors" (which included the PBM Defendants and/or their predecessors-in-interest)

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[134] OPTUMRX_JEFFCO_0603451; OPTUMRX_JEFFCO_0000014268; OPTUMRX_JEFFCO_0000184961.

[135] *Id.*

[136] OPTUMRX_JEFFCO_0000360057.

describing the agency's desire to work with them to develop policies and procedures to significantly reduce opioid abuse.[137] This notice advised all recipients that Medicare data show overutilization of prescription opioids that is "highly indicative of drug seeking behavior due to drug abuse or diversion."[138] The PBM Defendants received the notice and were aware of the need to take action to address the opioid crisis through the use of utilization management tools. While CMS acknowledged that some Part D sponsors were employing "claim-level" controls to try to prevent opioid misuse, CMS advised that these measures do not adequately address the opioid overutilization that concerned CMS and suggested that "beneficiary-level controls" are needed, including clinical upper thresholds for appropriate dosing, beneficiary-level utilization reports that identify unusual patterns of opioid use, and denial of payment for any claims that reflect amounts in excess of appropriate clinical thresholds that cannot be justified after review.[139]

434. In response to feedback generated by the September 2011 notice, CMS issued another notice in December 2011.[140] CMS assured sponsors in this notice that prompt pay regulations are not an impediment to their efforts to reduce overutilization and diversion of opioids because those regulations only apply to "clean claims" while prescriptions that raise concerns—for example, because they would

[137] *See* ESI_JEFFCOMO_000262220 (1/25/12).

[138] *Id.* at 1.

[139] *Id.* at 1-2.

[140] *See* ESI_JEFFCOMO_000262863 (1/16/12).

exceed appropriate clinical thresholds—are not "clean."[141] This notice also encouraged sponsors, including the PBM Defendants, to self-report instances of potential fraud or abuse (*e.g.*, drug-seeking behavior) and noted that mandatory reporting may be the subject of future rule-making.[142] And CMS also advised sponsors that, while wholesale prior authorization requirements may not be implemented for "protected class drugs," sponsors can "conduct retrospective reviews on . . . protected class drugs," and where such a review reveals that opioids are being diverted or misused, the sponsor "can require documentation to determine medical necessity and may deny payment for subsequent claims if insufficient evidence is obtained to substantiate" the legitimacy of the prior opioid prescriptions.[143] This notice further reminded sponsors, including the PBM Defendants, that they "may conduct appropriate consultations with physicians regarding treatment options and outcomes."[144] Finally, the December 2011 CMS notice suggested that sponsors should "encourage prescribers to prescribe in less than 30 days supplies" and "promote less than 30 day prescribing of drugs that are more susceptible to abuse or diversion, especially opioids."[145]

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[141] *Id.* at 1-2.

[142] *Id.* at 2.

[143] *Id.*

[144] *Id.* at 2.

[145] *Id.*at 3.

435. Likewise, in June 2012, CMS issued a draft guidance on improving drug utilization review controls.[146] In this guidance, CMS explained that, because of sponsor comments seeking clarification of what is expected, CMS was providing a "sample program" and "additional detail" on "how such a program could be implemented."[147] This sample program called for, among other things:

- Written policies and procedures that are updated and reviewed by plan's P&T Committee;
- Establishment of "methodology to identify potential opioid overutilizers based on drug claims data through clinical thresholds and prescription patterns set by the P&T committee that would trigger case management";
- A protocol to exclude from retrospective review persons who truly need significant amounts of opioids (cancer patients, palliative care);
- Regular communication with prescribers and beneficiaries about case management actions;
- A process for data sharing among sponsors when beneficiary/patient disenrolls voluntarily from a plan; and
- Policies and procedures for reporting to appropriate agencies when overutilization occurs.[148]

436. The CMS guidance also included sample form communications that sponsors can use in implementing programs to prevent overutilization and diversion of opioids.[149]

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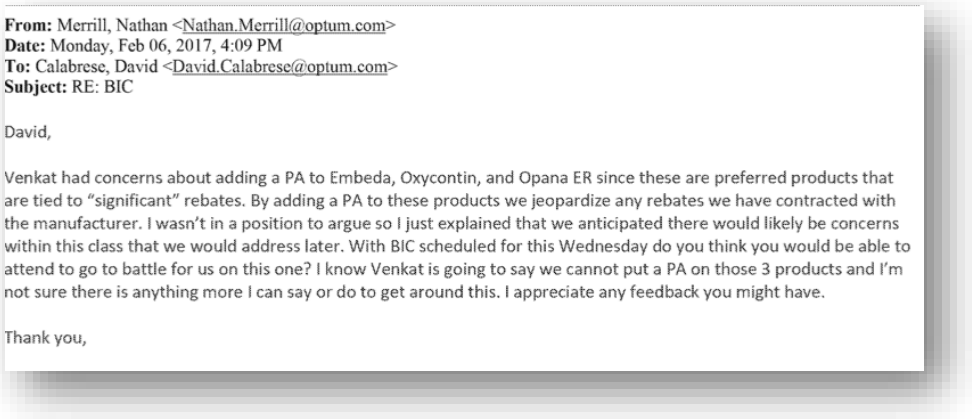
[146] *See* ESI_JEFFCOMO_000022947 (7/5/12).

[147] *Id.* at 1.

[148] *Id.* at 2-6.

[149] *Id.* at 8-14.

437. However, even with CMS calling attention to PBM Defendants' role and responsibility to prevent opioid misuse, Defendants' internal resistance to implementing policies and procedures to significantly reduce opioid abuse continued for years. For instance, in a February 6, 2017 email, Nathan Merrill, the OptumRx Manager of Clinical UM Operations, wrote to David Calabrese, the OptumRx Chief Pharmacy Officer, highlighting concerns with placing prior authorization limits on the opioids Embeda (Pfizer), OxyContin (Purdue), and Opana ER (Endo) because "these are preferred products that are tied to 'significant' rebates," and that "[b]y adding a [prior authorization] to these products we jeopardize any rebates we have contracted with the manufacturer."[150]



From: Merrill, Nathan <Nathan.Merrill@optum.com>
Date: Monday, Feb 06, 2017, 4:09 PM
To: Calabrese, David <David.Calabrese@optum.com>
Subject: RE: BIC

David,

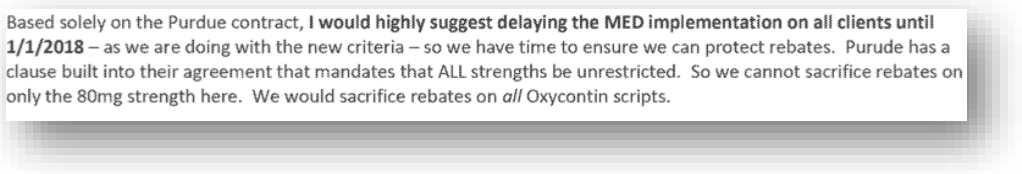
Venkat had concerns about adding a PA to Embeda, Oxycontin, and Opana ER since these are preferred products that are tied to "significant" rebates. By adding a PA to these products we jeopardize any rebates we have contracted with the manufacturer. I wasn't in a position to argue so I just explained that we anticipated there would likely be concerns within this class that we would address later. With BIC scheduled for this Wednesday do you think you would be able to attend to go to battle for us on this one? I know Venkat is going to say we cannot put a PA on those 3 products and I'm not sure there is anything more I can say or do to get around this. I appreciate any feedback you might have.

Thank you,

438. In a later 2017 email chain, Optum employees internally discussed whether they should implement a hard limit to morphine equivalent dosing ("MED") on OxyContin 80mg to align with the 2016 CDC Prescribing guidelines if it would mean loss of rebates. In an April 14, 2017 email from Brian Sabin, the Manager of Industry Relations, he responded they should delay implementing the formulary

[150] OPTUMRX_JEFFCO_0000366595 (2/6/17).

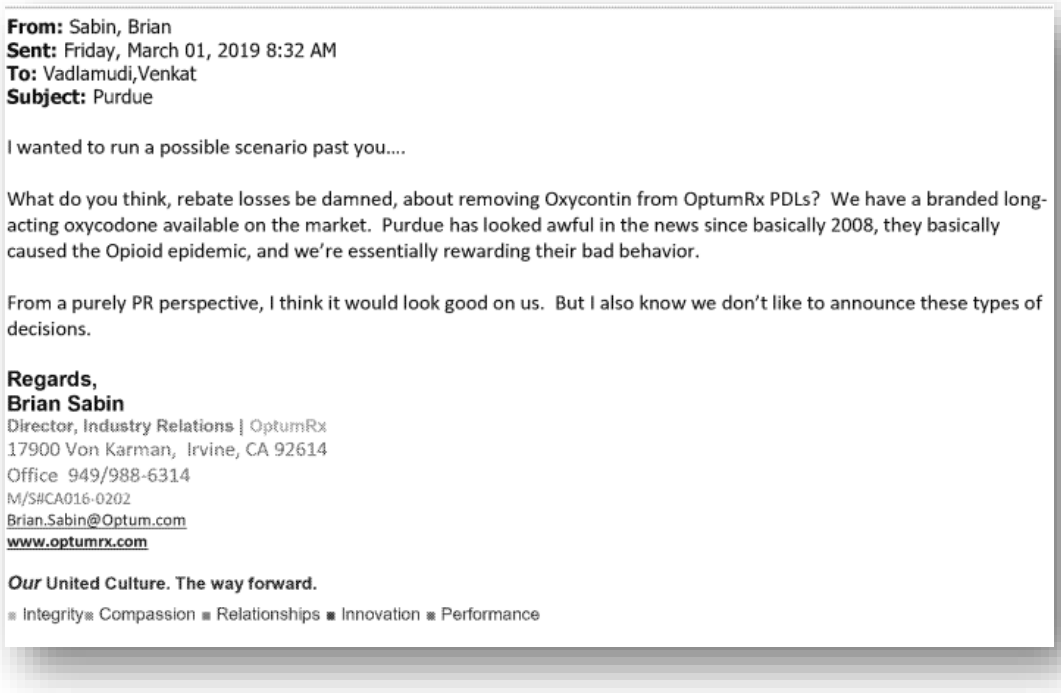
CDC MED limits on OxyContin 80mg to "ensure we protect rebates" because "we cannot sacrifice rebates on only the 80mg strength here" as that would mean Optum would "sacrifice rebates on *all* OxyContin scripts."[151]


Based solely on the Purdue contract, **I would highly suggest delaying the MED implementation on all clients until 1/1/2018** – as we are doing with the new criteria – so we have time to ensure we can protect rebates. Purude has a clause built into their agreement that mandates that ALL strengths be unrestricted. So we cannot sacrifice rebates on only the 80mg strength here. We would sacrifice rebates on *all* Oxycontin scripts.

439. Even as of 2019, Optum was still profiting from keeping OxyContin on its standard formularies. In a March 2019 email exchange, Optum Director of Industry Relations Brian Sabin asked Senior Director of Industry Relations Venkat Vadlamudi whether Optum should remove OxyContin from its formularies altogether, "rebate losses be damned," noting that Purdue "basically caused the Opioid epidemic" and Optum's continued inclusion of OxyContin on its formularies was "essentially rewarding their bad behavior." He added, "From a purely PR perspective, I think it would look good on us."[152]

[151] OPTUMRX_JEFFCO_0000107098 (4/14/17).

[152] OPTUMRX_JEFFCO_0000506200 (3/4/19).



From: Sabin, Brian
Sent: Friday, March 01, 2019 8:32 AM
To: Vadlamudi,Venkat
Subject: Purdue

I wanted to run a possible scenario past you....

What do you think, rebate losses be damned, about removing Oxycontin from OptumRx PDLs? We have a branded long-acting oxycodone available on the market. Purdue has looked awful in the news since basically 2008, they basically caused the Opioid epidemic, and we're essentially rewarding their bad behavior.

From a purely PR perspective, I think it would look good on us. But I also know we don't like to announce these types of decisions.

Regards,
Brian Sabin
Director, Industry Relations | OptumRx
17900 Von Karman, Irvine, CA 92614
Office 949/988-6314
M/S#CA016-0202
Brian.Sabin@Optum.com
www.optumrx.com

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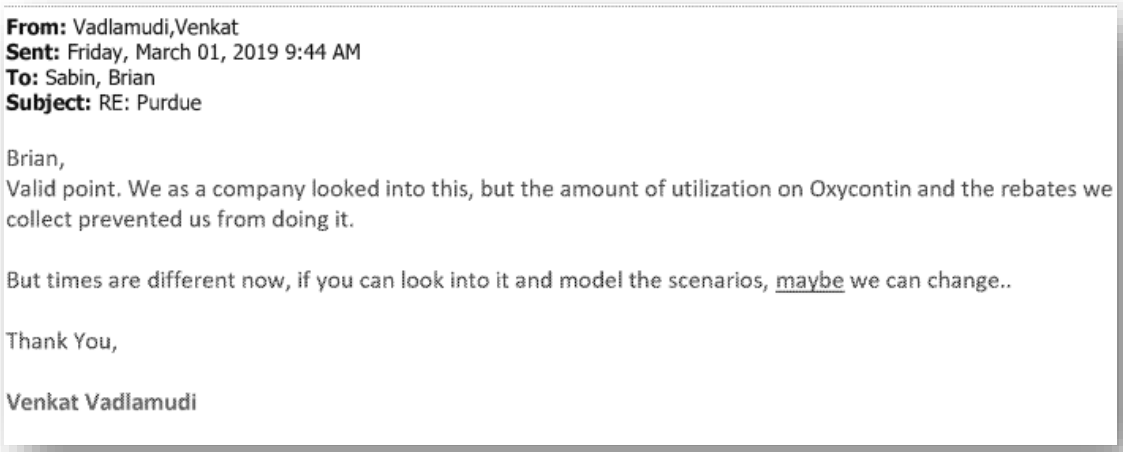
440. Senior Director Vadlamudi replied, "We as a company looked into this, but the amount of utilization on Oxycontin and the rebates we collect prevented us from doing it."[153] Vadlamudi then adds that "maybe we can change" if Sabin "can look into it and model the scenarios":[154]

[153] *Id.*

[154] *Id.*



From: Vadlamudi,Venkat
Sent: Friday, March 01, 2019 9:44 AM
To: Sabin, Brian
Subject: RE: Purdue

Brian,
Valid point. We as a company looked into this, but the amount of utilization on Oxycontin and the rebates we collect prevented us from doing it.

But times are different now, if you can look into it and model the scenarios, maybe we can change..

Thank You,

Venkat Vadlamudi

441. Express Scripts likewise resisted limits that threatened rebates and other fees. For example, in a 2017 email chain, several Express Scripts employees derided the fact that the effort to put a prior authorization limit on OxyContin had been overruled by the ESI Value Assessment Committee. Janelle Kuntz, the Express Scripts Clinical Director for the Office of Clinical Evaluation & Policy, stated that the decision "[w]as not sitting well with me at all," and wanted it escalated "to ensure that the rebate gain outweighs the likely erosion of our reputation." Nancy Pehl, Senior Director, Drug Evaluation Unit Office of Clinical Evaluation & Policy at Express Scripts, responded the same day that the decision "is really sad, really disheartening" and made "[n]o clinical sense to say the least."[155]

442. For years, Express Scripts' executives observed that efforts to address opioid overutilization with respect to Medicare were not being offered or implemented on the commercial side. In 2014, Snezana Mahon and Amanda Dwyer commented about the fact that "what is available in Medicare is not fully available in

[155] ESI_JEFFCOMO_000029940 (3/23/17).

Commercial."[156] Ms. Mahon commented that Express Scripts knew that it scored poorly in these areas and have been filling out response to an RFP for the last couple years to that effect. In response, Amanda Dwyer commented that it is "unfortunate that what is available in Medicare is not fully available in Commercial, and [Express Scripts] continue[s] to just be okay with lacking in these areas."[157] Ms. Mahon echoed these comments in 2016 during Express Scripts' "Opioid Summit" in discussing what Express Scripts needed to do to address inappropriate opioid utilization, stating, "CMS put in requirements that were [opioid] solutions that were not put into commercial because we didn't invest in the other lines of business."[158]

443. In sum, in exchange for lucrative financial benefits from the opioid manufacturers, Express Scripts and Optum have stoked the fires of the opioid epidemic by allowing unfettered access on their standard formularies to dangerous, highly addictive opioids with minimal, if any, restrictions.

444. That reality, however, has not deterred PBMs from publicly touting their unique ability to alter the course of the opioid epidemic.

445. On February 18, 2018, Snezana Mahon, Express Scripts Vice President of Clinical Product Development, testified before the United States Senate Committee on Health, Education, Labor and Pensions hearing titled, "The Opioid Crisis: The Role of Technology and Data in Preventing and Treating Addiction."

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[156] ESI_JEFFCOMO_000095166.

[157] *Id.*

[158] ESI_JEFFCOMO_000109001

During the hearing, Ms. Mahon testified about out how Express Scripts had the ability to "minimize early opioid exposure and prevent progression to overuse and abuse." Ms. Mahon further testified to Congress:

> Because Express Scripts interacts with patients, pharmacies, prescribers, and payers, our company is uniquely situated to collect data when patients receive and fill a prescription for an opioid under their pharmacy benefit. *We can leverage that data across the care continuum in order to design interventions aimed at preventing opioid addiction from beginning in the first place*. With 2 million Americans addicted to prescription narcotics, and more than 1,000 people treated daily in emergency departments for misusing prescription opioids, this is a $53 billion public health crisis.[159]

446. Likewise, in 2017, OptumRx announced, "By leveraging OptumRx's clinical, analytics and administrative services and its deep connections to those who can effect change—patients, providers and pharmacists—the company is uniquely positioned to help address the opioid epidemic."[160]

447. Optum's Chief Pharmacy Officer, David Calabrese, has made similar statements: "PBMs are uniquely positioned to connect and partner with physicians, pharmacists, patients, pharmaceutical manufacturers, health systems and other components of the industry and therefore are better able to drive improvements in education surrounding the dangers of opioid therapy, as well as the various tools available for constituents to positively change the course of this epidemic." Calabrese

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[159] Snezana Mahon, PharmD, *The Opioid Crisis: The Role of Technology and Data in Preventing and Treating* Addiction (February 27, 2018), https://www.help.senate.gov/imo/media/doc/Mahon.pdf (emphasis added).

[160] Optum, *OptumRx Opioid Risk Management Program Leads to Better Outcomes for Patients and Clients,* (Aug. 22, 2017), https://www.optum.com/about/news/optumrx-risk-management-program-leads-to-better-outcomes.html.

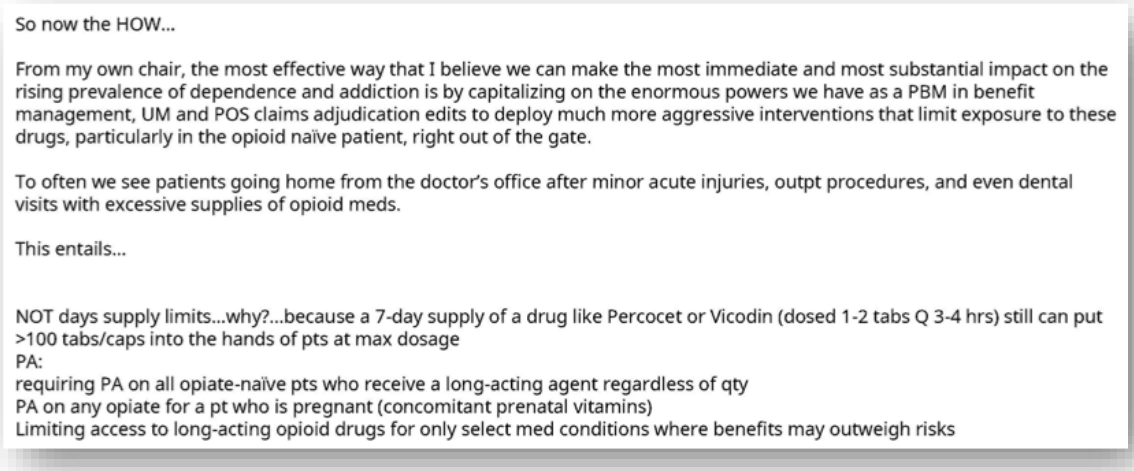
added, "Our nation's indiscriminate prescribing, dispensing, demand for, and consumption of prescription opioid drugs has led to a scenario in which we now consume more than 80% of the world's supply of prescription opioids and a corresponding death toll due to opioid overdose which is one of the highest in the world."[161]

448. In March 2017, Calabrese gave a talk at a PBM trade association conference titled "Confronting the Crisis We Brought Upon Ourselves: America's Opioid Abuse Epidemic," admitting that "[w]e are all accountable . . . and all part of the solution . . .":[162]

[161] Managed Healthcare, *Four PBM programs poised to rein in the opioid epidemic*, (Jan. 1, 2018), https://www.managedhealthcareexecutive.com/view/four-pbm-programs-poised-rein-opioid-epidemic.

[162] OPTUMRX_JEFFCO_0000017988 (3/24/17).

449. Calabrese's presentation discusses the "most effective" way to "[c]lose the [f]loodgates" on opioid abuse would be to "capitalize on the enormous powers we have as a PBM in benefit management . . . to deploy much more aggressive interventions that limit exposure to these drugs . . . right out of the gate":[163]



So now the HOW...

From my own chair, the most effective way that I believe we can make the most immediate and most substantial impact on the rising prevalence of dependence and addiction is by capitalizing on the enormous powers we have as a PBM in benefit management, UM and POS claims adjudication edits to deploy much more aggressive interventions that limit exposure to these drugs, particularly in the opioid naïve patient, right out of the gate.

To often we see patients going home from the doctor's office after minor acute injuries, outpt procedures, and even dental visits with excessive supplies of opioid meds.

This entails...

NOT days supply limits...why?...because a 7-day supply of a drug like Percocet or Vicodin (dosed 1-2 tabs Q 3-4 hrs) still can put >100 tabs/caps into the hands of pts at max dosage
PA:
requiring PA on all opiate-naïve pts who receive a long-acting agent regardless of qty
PA on any opiate for a pt who is pregnant (concomitant prenatal vitamins)
Limiting access to long-acting opioid drugs for only select med conditions where benefits may outweigh risks

450. Among the tools Calabrese suggests is the use of OptumRx's "predictive modeling capabilities [to identify at-risk patients and monitor physician prescribing patterns] that will allow us much greater leverage in getting ahead of the problems for our members, before it is too late."[164]

451. The data in Calabrese's presentation, which showed the severity of the epidemic and rampant noncompliance with the CDC's 2016 recommendations on opioid prescribing, were from Optum's own claims data.

[163] *Id.*

[164] *Id.*

452. Speaker notes from an OptumRx sales presentation from the same time period characterize the PBM response to the opioid crisis as a "delayed reaction," declaring that "we can no longer sit idly by and watch":

> Today we are in the midst of one of the most significant healthcare crises in our nation's history, and that is our nation's opioid abuse epidemic. …
>
> Sadly, *unlike other crises we've faced before, this one is unique in that it is one that we have largely brought upon ourselves*. How? Through the over-promotion and over-prescribing of these drugs by our pharm mfgs and physicians; *our delayed reaction in intervening as PBMs and MCOs as our death toll rose substantially*; and our lax attitudes as a society as a whole with regard to the acceptance; consumption; sharing; storage and propere [sic] disposal of these agents when prescribed to ourselves and our family members.
>
> Because we all share accountability, we at OptumRx, believe we are in a unique position now (unlike that of any of our competitors) to leverage the broad capabilities across our enterprise (Rx, BH, analytics, CM, etc...) and deliver the type of end-to-end solution suite that will deliver a positive impact in decreasing *the prevalence of OUD and the fatality rate that we can no longer sit idly by and watch to continue*.[165]

453. Despite having been "uniquely positioned" to change the trajectory of the opioid epidemic, the PBM Defendants instead sat "idly by" for years. Even when they began to take some steps to ostensibly address the crisis, Defendants themselves recognized that these measures were ineffective. For example, a July 2016 internal ESI memorandum about the upcoming "Opioid Summit" indicated that while ESI had "several tools and solutions to identify and manage opioids . . . our solutions are sometimes disjointed and lack coordinated approaches."[166] Similarly, a 2017 presentation described ESI's existing opioid solutions as "fragmented," "disjointed"

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[165] OPTUMRX_JEFFCO_0000206573 (3/8/17) (emphasis supplied).

[166] ESI_JEFFCOMO_000028723 (7/4/16).

and having "no clear value prop."[167] And although Optum mailed notice letters to "outlier prescribers" in late 2016, no providers were dismissed from the network as a result of the investigation, and Optum never conducted any follow-up analysis to determine whether the letters had any impact on prescribing.

b. The PBM Defendants chose not to use their "Drug Utilization Review" tools to address overprescribing, abuse and diversion

454. The PBM Defendants also had available to them their Drug Utilization Review ("DUR") programs to control the flow of opioids but chose not to use this tool either. Internal documents from the PBM Defendants show that rebate monies had a direct impact on how the PBM Defendants managed access to opioids, including their obligations to monitor on a real-time basis through concurrent drug utilization review that only safe and appropriate opioid prescriptions would be filled.

455. "Concurrent DUR" or "cDUR" involves the real-time evaluation of drug therapy and intervention, if necessary, while the patient is undergoing therapy, including screening at the point of sale for potential drug therapy problems due to therapeutic duplication, age/gender-related contraindications, over-utilization and under-utilization, drug-drug interactions, incorrect drug dosage or duration of drug therapy, drug-allergy contraindications, and clinical abuse/misuse.

456. But they refused to use cDUR to control opioid misuse because doing so would have impacted their revenue, including receipt of rebates, income generated from opioid dispensing, and other fees. For years, the PBM Defendants have failed to

[167] ESI_JEFFCOMO_000179506 (3/31/17).

deploy cDUR initiatives to ensure that only appropriate opioid prescriptions were being dispensed in pharmacies across the country (including in their own mail order pharmacies). This intentional refusal by the PBM Defendants permitted the dramatic increase in medically inappropriate prescribing and dispensing of prescription opioids that contributed to the fueling of the opioid epidemic.

457. Even when some clients attempted to place cDUR dosage limits on excessive use of opioids, Express Scripts and Optum colluded with the opioid manufacturers to push back.

458. Even when the FDA in 2013 removed the indication for use of long-acting narcotics to treat moderate pain, Express Scripts saw no reason to change its cDUR program, acknowledging that its strategy was "more focused on driving preferred products and managing quantities."[168] One ESI employee at the time described the FDA change as "kind of a non-event."[169]

459. Several years later, in 2016 when ESI tried to implement cDUR limits on Purdue's drugs, the manufacturer pushed back, reminding ESI that the cDUR limits (which would have restricted opioid use to acute pain, blocked opioids unless the use was for cancer or other approved uses, or required prior authorization for all opioids) would be in violation of its rebate agreement.

460. Optum, too, was unwilling to implement robust cDUR restrictions because doing so would impact its receipt of rebates. In 2017, when OptumRx tried

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[168] ESI_JEFFCOMO_000169781 (9/11/13).

[169] *Id*.

to implement changes which would have used cDUR to control inappropriate opioid usage, there was pushback because it would mean the loss of rebates. In response to these concerns, on March 24, 2017, SVP Calabrese raised the question whether, "[i]f our opioid mfg industry partners can't appreciate the magnitude of the problem we are facing [and] the immediacy of the need for intervention[,] . . . I would question whether they are the right partner for us longer term":[170]

From: Calabrese, David [mailto:David.Calabrese@optum.com]
Sent: Friday, March 24, 2017 7:19 AM
To: Rogers, Kent D
Cc: Gilbertson, Jenna M [From Catamaran]; Lahman, Robert C
Subject: RE: Morphine Equivalent Dosing (MED) Edits & Trade Implications

OK. Thanks.

If our opioid mfg industry partners can't appreciate the magnitude of the problem we are facing; the immediacy of the need for intervention; and the clinical value of our efforts here, I would question whether they are the right partner for us longer term.

461. Later that same day, Robert Lahman, OptumRx SVP Industry Relations, responded that "I agree with you but you also have to be mindful of our [rebate] contracts." Lahman also warned Calabrese to "[s]top with the attitude and help us make sure we are compliant with our contracts."[171]

462. Frustrated that OptumRx would delay the changes to its use of cDUR limits resulting from what he saw as "gross overprescribing and overpromotion of these medications . . . , and the countless deaths," Calabrese later that day sent an irate response to Lahman, telling him: "Maybe you should be the one to take a step

[170] OPTUMRX_JEFFCO_0000235659 (3/24/17).

[171] *Id.*

back and look at the bigger picture here. I need you on board with doing your job and convincing the [manufacturers] that we drive the ship here in terms of how their drugs get used, not them!"[172]

463. Even when products like Opana ER were being withdrawn from the market, OptumRx refused to put a PA in place that would have prevented new patients from starting on the drug because it would "put [Optum's] rebates at risk."[173]

[172] *Id.*

[173] OPTUMRX_JEFFCO_0000430032 (7/19/17).

From: Calabrese, David [mailto:David.Calabrese@optum.com]
Sent: Thursday, July 13, 2017 10:38 AM
To: Lahman, Robert C; Dutta, Sumit [From Catamaran]; Rogers, Kent D
Subject: RE: Clinical News Summary - Opana ER market withdrawal, NovoPen Echo recall, DepoCyt discontinuation, Alkeran first-time generic

The drug is being removed from the market for clinical safety reasons.

Why, in the best interest of the patients we serve, would we allow any new patient start on this drug between now and then??

From: Lahman, Robert C
Sent: Thursday, July 13, 2017 1:24 PM
To: Calabrese, David <David.Calabrese@optum.com>; Dutta, Sumit <Sumit.Dutta@optum.com>; Rogers, Kent D <kent.rogers@optum.com>

HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY OPTUMRX_JEFFCO_0000430032

Subject: RE: Clinical News Summary - Opana ER market withdrawal, NovoPen Echo recall, DepoCyt discontinuation, Alkeran first-time generic

We currently get rebates and that would put our rebates at risk. Why would we do this before 1/1?

Bob

From: Calabrese, David [mailto:David.Calabrese@optum.com]
Sent: Thursday, July 13, 2017 5:38 AM
To: Dutta, Sumit [From Catamaran]; Lahman, Robert C; Rogers, Kent D
Subject: FW: Clinical News Summary - Opana ER market withdrawal, NovoPen Echo recall, DepoCyt discontinuation, Alkeran first-time generic
Importance: High

Want to deploy an off-cycle PA ASAP to prevent any new starts from going on this product? All good with that?

c. The PBM Defendants failed to use their vast stores of data, their formulary and UM offerings, and their DURs to provide effective controls against diversion and/or to prevent the diversion and abuse of opioids

464. The PBM Defendants were uniquely situated to control against the abuse and diversion of opioids, but as described above, chose not to do so.

465. As described more fully below, OptumRx provides both PBM and mail-order dispensing services. In its capacity as a mail-order dispenser, OptumRx is (and is required to be) registered with the federal Drug Enforcement Agency ("DEA"). The

Controlled Substances Act ("CSA") and its implementing regulations require all registrants to provide "effective controls" against the diversion of controlled substances. 21 C.F.R. § 1301.71(a). Nothing in the CSA suggests that this obligation is limited to only certain aspects of a registrant's business. A retail pharmacy, for example, cannot satisfy its obligations by exercising controls at its dispensing counter if it is maintaining an open-air illegal drug market in its parking lot. The obligation to maintain effective controls against diversion applies to all of a registrant's activities.

466. OptumRx failed to maintain effective controls against diversion in the operation of its PBM services. On the contrary, as detailed above, at every turn OptumRx used its standard formularies, UM tools, and DUR programs to increase the supply of opioids, without regard to abuse or diversion of these drugs. OptumRx's operation of its standard formularies, UM tools, and DUR programs was thus in violation of its obligations as a CSA registrant to provide "effective controls" against diversion. This is especially true because, as detailed above, OptumRx *knew* that its policies resulted in diversion and *knew* that changes that it declined to make would have reduced oversupply and diversion.

467. Express Scripts used different corporate entities to operate its PBM and mail-order dispensing businesses. But Express Scripts knew that prescription opioids presented serious risks of abuse and diversion and knew that its mail-order pharmacy was required by the CSA to provide effective controls against diversion. Express Scripts also knew that it was in possession of massive amounts of data that could be

used to provide such effective controls, and also knew that it had a panoply of tools at its disposal – standard formularies, UM tools, and DUR programs – all of which could be used to reduce diversion. Even if the Express Scripts entities that provide PBM services are not themselves subject to DEA oversight, those entities had parallel responsibilities to operate their PBM services with appropriate care in light of the dangers of diversion that the CSA is designed to guard against. Any controls that Express Scripts Pharmacy, Inc.; ESI Mail Pharmacy, Inc. and Express Scripts Specialty Distribution Services, Inc. (all DEA registrants) provided (assuming there were any) could not be effective while its sister companies conducted their PBM activities so as to maximize the volume of opioid sales. Either way, Express Scripts had a duty to operate its PBM business in such a way as to minimize or reduce the risks that these dangerous drugs would be diverted. All of the data available to Express Scripts was also available to its mail-order dispensing affiliates, and those entities had a duty to use that data in maintaining effective controls against diversion, but they failed to do so.

E. Two Decades After They Knew Opioids Were Causing a Public Health Crisis, Express Scripts and Optum Finally Implemented Protocols to Address the Opioid Epidemic

468. After decades of working to increase opioid utilization, in 2017, due to mounting pressure from their clients and the federal government, Express Scripts and Optum finally implemented programs aimed at addressing opioid overutilization and abuse. Express Scripts' Advanced Opioid Management ("AOM") program started

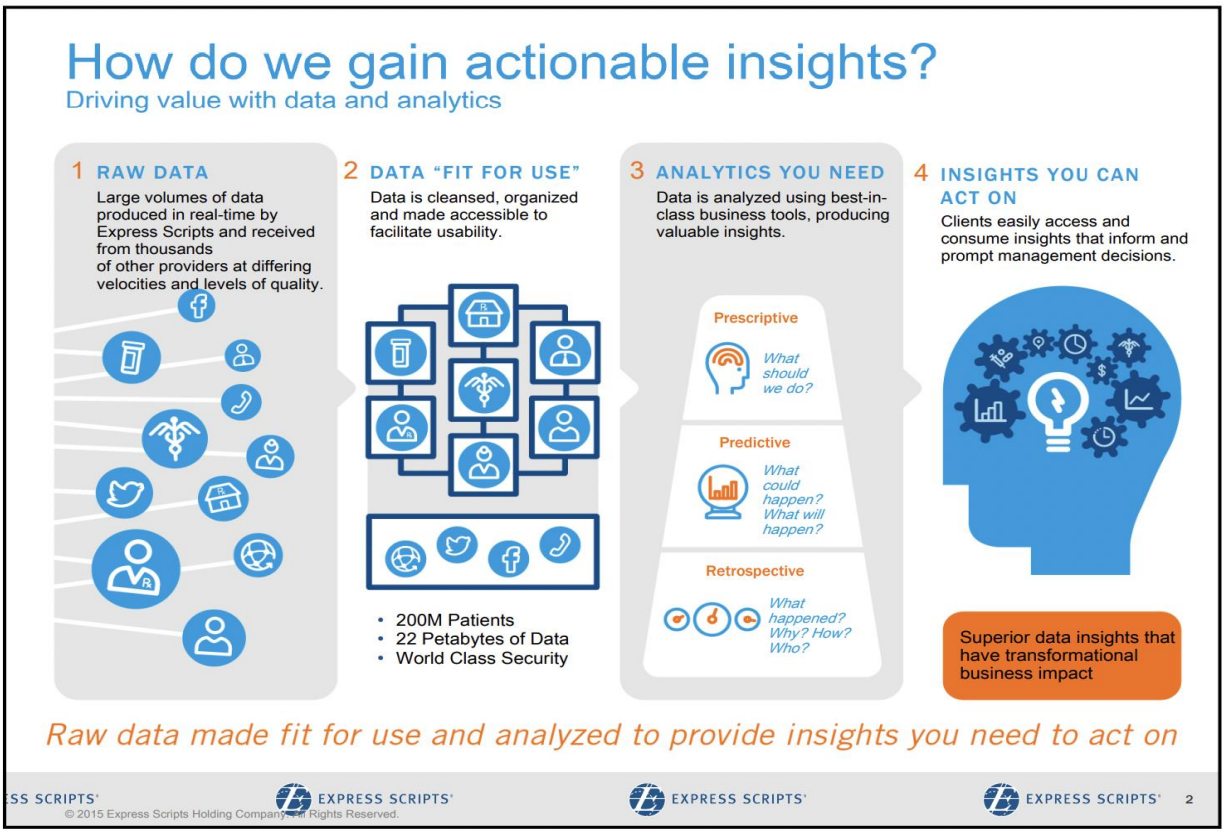
on September 1, 2017, and Optum's Opioid Risk Management ("ORM") program was offered starting in January 2018.

469. As discussed above, as major PBMs, Express Scripts and Optum undoubtedly had knowledge of the opioid crisis years, if not two decades, earlier.

470. Moreover, for years prior to actually implementing these programs, Express Scripts and Optum publicly touted their ability to translate the incredible amount of data it received into solutions to address pressing problems in healthcare. For example, in 2013 Forbes article titled "How Express Scripts Uses Analytics to Improve Patient Outcomes," Express Scripts Chief Information Officer, Gary Wimberly stated, "By filling 1.4 billion prescriptions per year, we have over 10 petabytes of useful data from which we can gain insights and for which we can develop solutions."[174]

471. Express Scripts client-facing presentations echoed Mr. Wimberly's statements:

[174] Stacy Dep. Ex. 8.



472. Yet, despite having access to petabytes of data for over a decade prior to rolling out the AOM (as discussed above) showing opioid overutilization and despite the PBM Defendants publicly promoting themselves as bastions of public health for years, the AOM program did not roll out to plan sponsors until 2017, at which point plans had to "buy up" to receive the program. Said another way, Express Scripts did not take action for *17 years after* it was aware of the prescription drug opioid crisis and not until after Express Scripts received an investigation inquiry from the United States Senates related to opioid overutilization and the CDC declared that addiction could occur between five days and one month.

473. As debuted on September 1, 2017, Express Scripts' AOM 1.0 program finally provided tools (such as prior authorizations) at the pharmacy level (referred

to as "point of sale" or "POS") that Express Scripts should have been offering for decades prior. Notably, the AOM program was the first time ESI had taken any direct steps to limit the quantity or flow of short acting opioids. AOM's new POS rules included the following:

- 200 MME cumulative per day limit for opioid Rx's;
- Above 200 MME requires a prior authorization (PA);
- Pharmacist is alerted at 90 MME.

474. The limits were "cumulative" across all opioid medications prescribed to the patient/member and limiting opioid naïve patients to 7-day supply for short acting opioid (SAO) prescriptions. Further, the Enhanced Prior Approval applied across all Long-Acting Opioids (LAO), whether generic or brand. In addition, a new patient required first fill of a short acting opioid before using a long-acting opioid. AOM also included non-utilization management elements such as proactive member education (letter after first fill), Opioid Disposal Bags, and Physician care alerts (messaging via EMR on MED and other issues).

475. Express Scripts stated that its AOM program was "designed to align with the [2016] Centers for Disease Control and Prevention Guidelines for Prescribing Opioids for Chronic Pain."[175] The program, however, did not align with the 2016 CDC Guidelines and in fact the featured limits were excessive and dangerous when compared to the CDC Guidelines. Nonetheless, Express Scripts claimed the following successes in first six months of the program:

[175] Blair Dep. Ex. 21.

- 59.5% reduction in average days' supply of opioids for first time users;
- 95.9% of prescriptions that were reprocessed because of UM edits were filled for 7-day supply or less;
- only 4.1% of prescriptions were filled for more than 7 days after prior authorization process was complete;
- 87% of new opioid prescriptions written for an LAO were subsequently filled with an SAO due to new enhanced PA program.[176]

476. As of September 2019, two years after the initial AOM rollout, Express Scripts claimed the following successes:

- 1.4 million fewer days' supply of opioids have been dispensed, while directing patients to safer, short-acting alternatives;[177]
- 40.6% reduction in average MME for new opioid users;
- 77% of patients prescribed an LAO as initial therapy were redirected to an SAO;
- 95.8% "success rate" of new members being dispensed an opioid claim at or below 90 MME.[178]

477. Subsequent AOM enhancements added new limits on fentanyl products and opioid adjacent therapy quantity limits, as well as:

- "Initial fill days' supply rule for adults initiating opioid therapy limited to a 7-days' supply for members' first 4 fills, requiring a prior authorization to exceed 28-days' supply in a 60-day period."[179]

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[176] Stettin Dep. Ex. 5.

[177] Express Scripts, *17.4 Million Americans Protected from a Nationwide Health Crisis,* https://www.express-scripts.com/corporate/solutions/improving-health#advanced-opioid-management (last accessed Nov. 14, 2023).

[178] Stettin Dep. Ex 12.

[179] Blair Dep. Ex. 21.

- "[L]imiting the morphine equivalent dosing to 90 MME for patients starting on opioids. Existing users are limited to 200 MME, unless they receive a prior authorization for a higher dosage."[180]

478. By 2019, 17.4 million Express Scripts covered lives were enrolled in the AOM.

479. Optum began rolling out its own program in mid-2017, although key features did not launch until January 2018 due to concerns about OxyContin rebate impact. Optum's Opioid Risk Management offered a "Base Offering" which was the standard program that applied to all PBM clients at no additional fee.[181] There was no opt-in required.

480. The ORM also included optional "Add-On components" which included narrow refill limits, hard edits as opposed to soft edits that were included in the Base Offering, and additional quantity limits on all LAOs.[182]

481. The ORM Buy Up Clinical Programs consisted of targeted clinical programs that supplement the previous ORM components to ensure "maximum oversight and prevention of abuse or misuse." These programs each had an accompanying fee and included:

- Educational support for identified members;
- Retrospective abused medication review, which included a daily claims review for concerning utilization patterns; and

[180] *Id.*

[181] OPTUMRX_JEFFCO_0000392019.

[182] *Id.*

- Intensive case management, which identified the highest risk members with potential for abuse.

482. The ORM had a significant impact on opioid utilization across OptumRx's book of business. Five months after the soft launch of the ORM program, it achieved:

- 21% reduction in first-fill prescriptions exceeding the CDC dosing guidelines of <50 MED per day. This translated to a 93% compliance rate with CDC safe dosing recommendations;
- 11% reduction in first-fill acute opioid prescriptions written for durations in excess of CDC-recommended 7-day supply maximum, translating to a 92 percent compliance to safe duration;
- 5% decrease in opioid prescriptions for current chronic opioid utilizers issued for >90mg MED resulting in 97 percent compliance to safe dosing;
- 14% reduction in average dose across all short-acting opioid prescriptions; and
- 12% reduction in overall volume of short-acting opioid prescriptions.

483. Notably, Express Scripts and Optum could have implemented these opioid reducing measures at any point over the past two decades as they tracked the opioid epidemic unfolding across the country. Quantity limits and prior authorizations have been used to control drug utilization since before Express Scripts and Optum were PBM. And the PBM Defendants have been using step therapy since the late 1990s.

484. Yet, Express Scripts and Optum failed to implement their opioid programs for over a decade after their own reports, studies, and clients were alerting them to the need for an "aggressive" policy to address "rampant abuse and inappropriate" opioid use. Had Express Scripts and Optum created effective protocols

to address the opioid overutilization—such as those implemented in 2017—when they first knew these drugs were causing a public health crisis, they could have significantly reduced the amount of opioids dispensed throughout the country, including in Plaintiff's Community, and reduced the harm caused by the opioid epidemic.

F. Even After Implementing its Opioid Risk Management Program, Optum Continued Promoting Uncontrolled Opioid Sales Through Its Cash Card and Discount Card Businesses

485. Optum also collects set administrative fees for every opioid paid for with either its own discard cash service or by one of its administered cash cards—which are governed by either Optum Perks, LLC or Optum Discount Card Services, LLC. Cash cards do not have to adhere to formularies, nor do they have traditional utilization management controls. Cash cards played a significant role in the opioid epidemic, as they allowed patients that submitted prescriptions which exceeded their insurance plan limits a cheaper way to access opioids. Cash cards could be used by anyone to purchase opioids—including individuals who do not receive benefits from Optum or UnitedHealth Group. Optum counts individuals not receiving benefits from Optum nor United, but still utilizing its administered cash cards, as "members" of Optum. Optum receives administrative fees and other revenue from each opioid prescription paid for with an Optum-administered cash card. Optum issues cash cards for opioids despite knowing that this allows individuals an "end run around" controls built into Optum and other payors' formularies.[183] Further, and most

[183] OPTUMRX_JEFFCO_0000475440.

importantly, cash cards are not subject to any limits, exclusions or Prior Authorization controls since members pay the entire amount of the discounted claim.

486. Optum's cash card business focus took root in approximately 2015 when it realized that an expanded Cash Card/Pharmacy Discount service was an opportunity for revenue growth (and coinciding with the Catamaran acquisition since Catamaran had a significant cash card business). This included partnering with manufacturers, including opioid manufacturers, to further empower its cash card business.[184] They explicitly communicated that their cash card business included a lack of opioid controls.[185] Collegium, an opioid manufacturer, declined to participate in Optum's cash card program due to the lack of opioid controls.

487. At the same time, Optum was advertising and encouraging individuals—whether they were Optum or United members or not—to use its various administered cash card and discount programs to purchase opioids.

488. In 2017, while OptumRx was publicly touting its new Opioid Risk Management Program, internal documents showed that Optum was unwilling to control any prescriptions administered by Optum Perks or Optum Discount Card Services, and wanted to show that there were "no restrictions on cash cards, ever."[186] When presented with the opportunity to block opioids on its cash cards in 2017, Optum calculated that it would cost the business $26 million per year and as a result,

[184] OPTUMRX_JEFFCO_0000516126; OPTUMRX_JEFFCO_0000502380.

[185] OPTUMRX_JEFFCO_0000261979.

[186] OPTUMRX_JEFFCO0000236339.

decided not to block the use of cash cards for opioid claims. By 2018, Optum served over 3.6 million cash card "members."

489. Despite Optum's public-facing commitment to fighting the opioid epidemic, in June 2018, Optum refused to block opioid adjudication on its suite of cash cards. This included a refusal by Optum, its affiliates, and its marketing partners to cease advertising the use of Optum's suite of discount card pricing tools to pay for opioid prescriptions. The stated reason for this refusal was it would "cut into it [sic] revenue/the admin fees Optum collects regarding opioids."[187]

490. Optum was fully aware its cash cards were being used to abuse, divert, and misuse opioids at that time, including in Missouri. For example, in 2019, David Calabrese wanted to know Optum's exposure when the FBI charged dozens of medical practitioners and pharmacies throughout the country for the illegal prescribing of opioids.[188] An analysis of those "exposure" claims showed a large number of these were cash card claims administered by OptumRx.[189]

491. Optum's cash card business reimbursed claims for opioids in Missouri during the relevant time period and were part of Optum's misconduct that gave rise to the opioid epidemic in Missouri.

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[187] OPTUMRX_JEFFCO_00006830937.

[188] OPTUMRX_JEFFCO_0000604618.

[189] OPTUMRX JEFFCO 0000604271.

VI. As Mail Order Pharmacies, Express Scripts and Optum Dispensed Opioids in Violation of the Controlled Substances Act, Missouri law and the Missouri Comprehensive Drug Control Act.

A. The Applicable Statutes

492. In March 2016, the CDC, in order to reduce opioid addiction, overdoses, and deaths, published specific recommendations for clinicians who prescribe opioids outside of cancer treatment, palliative care, and end-of-life care. The CDC recommendations are based on "[s]cientific research [that] has identified high-risk prescribing practices that have contributed to the overdose epidemic (*e.g.*, high-dose prescribing, overlapping opioid and benzodiazepine prescriptions, and extended-release/long-acting opioids for acute pain)."[190]

493. Congress has found that pharmacies share responsibility for the crisis: "The opioid epidemic . . . has arisen, in part, from the diversion of prescription opioids through illegal dispensing practices at pharmacies."[191]

494. Defendants knowingly violated their duties under the federal Controlled Substances Act ("CSA") and its implementing regulations, the Missouri Comprehensive Drug Control Act and its implementing regulations, and Missouri state pharmacy laws and regulations including but not limited to 21 U.S.C.A. §§ 829,

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[190] *Id.* at 3.

[191] U.S. Senate Homeland Sec. & Governmental Aff. Comm., Ranking Member's Off., *Fueling an Epidemic: A Flood of 1.6 Billion Doses of Opioids into Missouri and the Need for Stronger DEA Enforcement,* at p. 4 (July 12, 2017) https://www.hsgac.senate.gov/wp-content/uploads/imo/media/doc/REPORT-Fueling%20an%20Epidemic-A%20Flood%20of%201.6%20Billion%20Doses%20of%20Opioids%20into%20Missouri%20and%20the%20Need%20for%20Stronger%20DEA%20Enforcement.pdf.

841 842; 21 C.F.R. §§ 1301.71, 1306.04, 1306.06; Mo. Rev. Stat. § 195.030, Mo. Rev. Stat. § 195.040, Mo. Rev. Stat. § 338.210, Mo. Rev. Stat. § 338.240, Mo. Rev. Stat. § 338.250, Mo. CSR 2220-2.010, Mo. CSR 2220-2.011, Mo. CSR 2220-2.013, and Mo. CSR 2220-2.195, ignoring their obligation to provide effective controls against diversion.

1. The Controlled Substances Act and Missouri Comprehensive Drug Control Act

495. The CSA and its implementing regulations govern the manufacture, distribution, and dispensation of controlled substances in the United States. From the outset, Congress recognized the importance of preventing the diversion of drugs from legitimate to illegitimate uses. The CSA accordingly establishes a closed regulatory system under which it is unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.[192]

496. The CSA categorizes controlled substances in five "Schedules."

497. Schedule II (also called herein CII) contains drugs with "a high potential for abuse" that "may lead to severe psychological or physical dependence," but nonetheless have "a currently accepted medical use in treatment."[193]

498. Schedule III contains drugs in which, although the abuse potential is less than a Schedule II drug, such abuse may lead to moderate "physical dependence

[192] *See* 21 U.S.C. § 841(a).

[193] 21 U.S.C. § 812(b)(2).

or high psychological dependence." Schedule III drugs also have "a currently accepted medical use."[194]

499. Schedule IV contains drugs that, although having a lower abuse potential than Schedule III drugs, still may lead to a physical or psychological dependence when abused.[195]

500. Schedule V contains drugs that, although having a lower abuse potential than Schedule IV drugs, still may lead to a physical or psychological dependence when abused.[196]

501. The CSA makes it "unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance" except as specifically authorized.[197]

502. Accordingly, the CSA requires those who manufacture, distribute, or dispense controlled substances to obtain a registration from the DEA.[198] A registrant is only permitted to dispense or distribute controlled substances "to the extent authorized by their registration and in conformity with the [CSA]."[199]

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[194] 21 U.S.C. § 812(b)(3).

[195] 21 U.S.C. § 812(b)(4).

[196] 21 U.S.C. § 812(b)(5).

[197] 21 U.S.C. § 841(a)(1).

[198] 21 U.S.C. § 822(a).

[199] 21 U.S.C. § 822(b).

503. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA.[200]

504. At all times relevant to this Complaint, Defendants have registered their mail order pharmacies with the DEA in Schedule II–V controlled substances. Those DEA registrations authorize Defendants'-owned pharmacies to "dispense" controlled substances, which "means to deliver a controlled substance to an ultimate user … by, or pursuant to the lawful order of, a practitioner."[201]

505. In the case of Express Scripts, the entities that are registered with the DEA are Express Scripts Pharmacy, Inc.; ESI Mail Pharmacy, Inc. and Express Scripts Specialty Distribution Services, Inc. In the case of Optum, the registered entity is OptumRx, the same entity that performs PBM services.

506. Agents and employees of a registered manufacturer, distributor, or dispenser of controlled substances, such as a pharmacist employed by a registered mail order pharmacy like those owned by Defendants, are not required to register with the DEA "if such agent or employee is acting in the usual course of his business or employment."[202]

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[200] 21 U.S.C. § 829.

[201] 21 U.S.C. § 802(10), *accord* 21 U.S.C. § 823(f).

[202] 21 U.S.C. § 822(c)(1).

507. Under the CSA, the lawful dispensing of controlled substances is governed by 28 U.S.C. § 829 and more specifically in Part 1306 of the CSA's implementing regulations.[203]

508. Unless dispensed directly by a non-pharmacist practitioner, no Schedule II controlled substance may be dispensed without the written prescription of a practitioner, such as a physician, except in an emergency.[204] Similarly, unless directly dispensed, no Schedule III or IV controlled substance may be dispensed without a written or oral prescription from a practitioner.[205]

509. Such a prescription for a controlled substance may only be issued by an individual who is (a) "authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession" and (b) registered with the DEA.[206]

510. A prescription, whether written or oral, is legally valid under the CSA *only* if it is issued for "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[207] Moreover, "[a]n order purporting to be a prescription issued not in the usual course of professional treatment … is not a prescription within the meaning and intent of [21 U.S.C. § 829] and the person knowingly filling such a purported prescription, as well as the person

[203] *See generally* 21 C.F.R. § 1306.

[204] 21 U.S.C. § 829(a).

[205] 21 U.S.C. § 829(b).

[206] 21 U.S.C. § 822; 21 C.F.R. § 1306.03.

[207] 21 C.F.R. § 1306.04(a).

issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances."[208]

511. As a result, the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."[209] Thus, a pharmacist may not fill a controlled substance prescription unless it has been issued for a legitimate medical purpose.

512. Moreover, "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually, or employed in a registered pharmacy…."[210]

513. Pharmacists are therefore permitted to dispense a controlled substance in any given instance if, *but only if*, such dispensing would be in accordance with a generally accepted, objective standard of practice—*i.e.,* "the usual course of his [or her] professional practice" of pharmacy.[211]

514. Consequently, a pharmacist is required to refuse to fill a prescription if he or she knows or has reason to know that the prescription was not written for a legitimate medical purpose.[212]

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[208] *Id.*

[209] *Id.*

[210] 21 C.F.R. § 1306.06.

[211] *Id.*

[212] *See* 21 C.F.R. §§ 1306.04, 1306.06.

515. Unlawful dispensing of controlled substances by a pharmacist may subject the pharmacy or pharmacist to criminal actions and to civil enforcement actions for money penalties or injunctions.[213]

516. A pharmacy also needs to know there is a corresponding responsibility for the pharmacist who fills the prescription.[214] The pharmacist has a legal duty to recognize "red flags" or warning signs that raise (or should raise) a reasonable suspicion that a prescription for a controlled substance is not legitimate. The existence of such indicia obligates the pharmacist to conduct a sufficient investigation to determine that the prescription is actually legitimate before dispensing. A pharmacist's corresponding responsibility extends to the pharmacy itself.

517. A pharmacy's registration can be revoked because its pharmacists have violated the corresponding responsibility rule and both the pharmacy and pharmacists may be the subject of further discipline.[215]

518. In addition to the CSA, Defendants were also required to comply with Missouri controlled substances law and pharmacy regulations, including, but not limited to, Mo. Rev. Stat. §§ 195.030, 195.040, 338.210, 338.240, 338.250; and Mo.

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[213] 21 U.S.C. §§ 842, 843.

[214] United States Department of Justice, Drug Enforcement Administration Office of Diversion Control, *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* (Rev. 2020).

[215] United States Department of Justice, Drug Enforcement Administration Office of Diversion Control, *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* (Rev. 2020) (citing *Jones Total Healthcare, L.L.C., v. DEA*, 881 F.3d 823 (11th Cir. 2018)).

CSR 2220-2.010, Mo. CSR 2220-2.011, Mo. CSR 2220-2.013, and Mo. CSR 2220-2.195. Express Scripts and Optum failed to meet these obligations.

2. Pharmacies Are Obligated Not to Fill Prescriptions Until All Red Flags Are Resolved

519. A pharmacy cannot ignore red flags indicative of abuse and diversion. On the contrary, "a pharmacist is obligated to refuse to fill a prescription if he knows or has reason to know that the prescription was not written for a legitimate medical purpose."[216] "[W]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid actual knowledge of the real purpose of the prescriptions."[217] Thus, § 1306.064 requires "pharmacists [to] use common sense and professional judgment," which includes paying attention to the "number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment," the number of doctors writing prescriptions and whether the drugs prescribed have a high rate of abuse or diversion.[218] "When [pharmacists'] suspicions are aroused as reasonable

[216] Medic-Aid Pharmacy, Revocation of Registration, 55 Fed. Reg. 30,043-01, 30,044, 1990 WL 328750 (Dep't of Just. July 24, 1990).

[217] East Main Street Pharmacy, Affirmance of Suspension Order, 75 Fed. Reg. 66,149-01, 66,150, 2010 WL 4218766 (Dep't of Just. Oct. 27, 2010).

[218] Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy, Inc., Revocation of Registration, 55 Fed. Reg. 4,729-01, 4,730, 1990 WL 352775 (Dep't of Just. Feb. 9, 1990).

professionals," they must at least verify the prescription's propriety, and if not satisfied by the answer they must "refuse to dispense."[219]

520. Courts, too, have recognized the obligation of pharmacies not to dispense until red flags are resolved.[220] In *Medicine Shoppe-Jonesborough*, the Sixth Circuit affirmed a pharmacy's liability for filling false or fraudulent prescriptions for controlled substances, concluding that the pharmacy violated § 829 of the CSA and 21 C.F.R. § 1306.04. The Court held "[t]he CSA forbids a pharmacy to dispense a Schedule II, III, or IV controlled substance without a prescription, 21 U.S.C. § 829(a)-(b), which 'must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,' 21 C.F.R. § 1306.04(a)."[221] Prescriptions that "involved excessive" quantities of drugs and "remedies outside the prescriber's ordinary area of practice" "should have raised red flags at Medicine Shoppe."[222] "By filling these prescriptions anyway. . . the pharmacy

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[219] *Id.*; *see also* Townwood Pharmacy, Revocation of Registration, 63 Fed. Reg. 8,477-04, 1998 WL 64863 (Dep't of Justice Feb. 19, 1998); Grider Drug No. 1 & Grider Drug No. 2, Decision & Order, 77 Fed. Reg. 44,070-01, 2012 WL 3027634 (Dep't of Justice July 26, 2012); The Medicine Dropper, Revocation of Registration 76 Fed. Reg. 20,039-01, 2011 WL 1343276 (Dep't of Justice Apr. 11, 2011); Medicine Shoppe-Jonesborough, Revocation of Registration, 73 Fed. Reg. 364-01, 2008 WL 34619 (Dep't of Justice Jan. 2, 2008); United Prescriptions Services, Inc., Revocation of Registration, 72 Fed. Reg. 50,397- 01, 50,407-8, 2007 WL 2455578 (Dep't of Just. Aug. 31, 2007).

[220] *See Med. Shoppe-Jonesborough v. Drug Enf't Admin.*, 300 F. App'x 409, 413-14 (6th Cir. 2008); *United States v. Henry*, 727 F.2d 1373, 1378-79 (5th Cir. 1984); *Holiday CVS, L.L.C. v. Holder*, 839 F.Supp.2d 145, 160 (D.D.C. 2012).

[221] *Med. Shoppe-Jonesborough*, 300 F. App'x at 412.

[222] *Id.* at 413.

not only violated its duties under federal (and state) law to ensure that only proper prescriptions were filled but also put public health and safety at risk."[223]

521. The MDL Court has addressed this very issue. The Court unequivocally stated that "[t]here is no question that dispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances."[224]

522. In fact, the MDL Court found that the corporate parents of chain pharmacies have an affirmative obligation under the CSA to "design and implement systems, policies, or procedures to identify red flag prescriptions."[225] The Court reasoned that pharmacies "cannot collect data as required by the statute, employ a licensed pharmacist as required by the statute, identify red flags as required by Agency decisions, but then do nothing with their collected data and leave their pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled. Possessing, yet doing nothing with, information about possible diversion would actually facilitate diversion, and thus violate the CSA's fundamental mandate that '[a]ll applicants and registrants shall provide effective controls and procedures

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[223] *Id.*

[224] *In re Nat'l Prescription Opiate Litig.*, 477 F. Supp. 3d 613, 629 (N.D. Ohio 2020), clarified on denial of reconsideration, No. 1:17-MD-2804, 2020 WL 5642173 (N.D. Ohio Sept. 22, 2020). *See also City and Cnty. Of San Francisco v. Purdue Pharma L.P.*, 620 F.Supp. 3d 936, 960 (N.D. Cal. 2022).

[225] *In re Nat'l Prescription Opiate Litig.*, 477 F. Supp. at 630.

to guard against theft and diversion of controlled substances.'" 21 C.F.R. § 1301.71(a) (emphasis added)."[226]

3. The CSA and Missouri Comprehensive Drug Control Act Apply to All Persons Who Dispense Controlled Substances

523. Courts have found that because the plain language of § 842 extends its requirements to "all persons," registrants and non-registrants alike are responsible for complying with the law.[227] Importantly, in those cases, the courts found that because the pharmacy owners, who were not registrants, essentially operated the facilities on a day-to-day basis, they were not exempted from the requirements of Section 842.[228]

524. At least one court has explicitly held that a non-registrant pharmacy owner can be held liable for dispensing controlled substances without valid prescriptions. In *United States v. City Pharmacy*, the court found that the owner of the pharmacy could be held liable in his personal capacity for violations of Section

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[226] *Id.*

[227] *See United States v. Blanton*, 730 F.2d 1425, 1434 (11th Cir. 1984) (Section 842(a)(5) applied to a physician who was not properly registered with the DEA); *United States v. Clinical Leasing Serv., Inc.*, 759 F. Supp. 310, 313-14 (E.D. La. 1990), *aff'd*, 925 F.2d 120 (5th Cir. 1991) ("Had Congress intended to limit the applicability of § 842(a)(5) to registrants only, it would have done so"); *United States v. Stidham*, 938 F. Supp. 808, 814 (S.D. Ala. 1996); *United States v. Poulin*, 926 F. Supp. 246, 250, 253 (D. Mass. 1996).

[228] *Stidman*, 938 F. Supp. at 809, 814 (the owner of a clinic, who was not a registrant, could be liable because he "shouldered [the] responsibility [to provide a system for the control of drug traffic and to prevent the abuse of drugs] and derived the benefits and profits from operating a methadone clinic."); *Poulin*, 926 F. Supp. at 249, 253 ("Although Mattapoisett Pharmacy, Inc. was listed as the registrant, the statute specifically makes the stated obligations to produce required records applicable to all persons, not simply to registrants.").

842(a)(1) even though he was not a registrant and the pharmacies he owned were separately incorporated.[229] The United States brought an action alleging that City Pharmacy LLC and City Pharmacy of Charles Town, Inc. violated Section 842(a)(1) by filling illegitimate prescriptions for controlled substances that raised one or more red flags, such as customers traveling long distances or customer receiving drug cocktails.[230]

525. The court held that Section "842(a)(1) applies to non-registrants."[231] The court continued, explaining that "because part C of the CSA applies broadly to all persons involved in the manufacture, distribution, and dispensing of controlled substances, including lay-persons, defendant Lewis may potentially be held liable for his conduct."[232] To support its conclusion, the court concentrated on defendant Lewis' involvement with the pharmacies at issue, looking specifically at his investment of the funds to organize and open the pharmacy, the active role he played in the management of the pharmacies, including overseeing the finances of the pharmacies, managing personnel, and delivering prescriptions to customers.

526. The *City Pharmacy* court also found that the individual defendant could not use the pharmacies' separate incorporation to shield himself from CSA liability. Evaluating various legal mechanisms for piercing the corporate form, the court

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[229] *United States v. City Pharmacy, LLC*, No. 3:16-CV-24, 2016 WL 9045859, at *4 (N.D. W.Va. Dec. 19, 2016).

[230] *Id*. at *1.

[231] *Id*. at *2 (citing *United States v. Moore*, 423 U.S. 122, 134 n.11 (1975) and *United States v. Stidham*, 938 F.Supp. 808, 813-814 (S.D. Ala. 1996)).

[232] *Id*. at *3.

concluded that the pharmacies "were being used to evade the legal requirements within and undermine the public policy foundations of the CSA."[233] Thus, the court held, "given the nature of these criminally-grounded allegations, it is not a defense to liability in this case for defendant Lewis to assert that he is shielded by the corporate form. [The pharmacies] were allegedly the entities used to evade and subvert the requirements of the CSA."[234]

527. Just like the defendant in *City Pharmacy*, as alleged more fully herein, Defendants have invested the funds to organize and open their mail order pharmacies and play a very active role in the management of those pharmacies, including overseeing the finances of the pharmacies, managing personnel, and delivering prescriptions to customers.

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[233] *Id*. at *4.

[234] *Id*.; *see also Poulin*, 926 F. Supp. at 253 *("*Mattapoisett Pharmacy, Inc. is also the alter ego of its sole owner, David Poulin, and thus David Poulin cannot use the corporate name to shield himself from personal liability."); S & S Pharmacy, Denial of Registration, 46 Fed. Reg. 13,051-03, 13,052, 1981 WL 96125 (Dep't of Justice Feb. 19, 1981) ("[T]he Administrator has in the past looked behind the corporate-veil to revoke or deny a registration when a responsible official of a corporate registrant has been convicted of violating the laws relating to controlled substances."); *United States v. Robinson*, No. 12-20319-CIV, 2012 WL 3984786, at *7 (S.D. Fla. Sept. 11, 2012), (finding a non-registrant owner of a pharmacy could be held liable for violations of Section 842 because the defendant was "alleged to have had responsibility over the controlled substances" and holding that "[w]here corporate officers have been in a position to prevent or correct the violations at issue, courts have found that there is individual liability under the [Section 842], which plainly applies to all 'persons.'"); *United States v. Ahmad*, No. 4:15CV-181-JM, 2016 WL 11645908, at *3 (E.D. Ark. May 2, 2016), *aff'd sub nom. United States v. United Pain Care, Ltd.*, 747 F. App'x 439 (8th Cir. 2019) (an owner receiving the "benefits and profit" of a pharmacy, but who was not a registrant or a medical professional, can be liable for violations of the CSA because he was still "responsible for making sure that [CSA] requirements were met.").

B. Defendants Violated the Controlled Substances Act, Missouri law, and the Missouri Comprehensive Drug Control Act

528. At all times material hereto, DEA registrants like the PBM Defendants had the duty to "provide effective controls and procedures to guard against theft and diversion of controlled substances."[235] Diversion includes the use of medication outside the usual course of professional practice.

529. The DEA has repeatedly emphasized that, as DEA registrants, pharmacies like those owned by the PBM Defendants are required to implement systems that will detect and prevent abuse and diversion and must monitor for red flags of abuse and diversion. The DEA has also repeatedly affirmed the obligations of pharmacies to maintain effective controls against abuse and diversion in regulatory action after regulatory action.[236] According to the DEA, pharmacists are the "[l]ast line of defense."[237]

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[235] 21 C.F.R. § 1301.71(a).

[236] *See, e.g.*, Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195, Decision & Order, 77 Fed. Reg. 62,316-01, 2012 WL 4832770 (Dep't of Justice Oct. 12, 2012); East Main Street Pharmacy, Affirmance of Suspension Order, 75 Fed. Reg. 66,149-01, 2010 WL 4218766 (Dep't of Justice Oct. 27, 2010); *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145 (D.D.C. 2012); Townwood Pharmacy, Revocation of Registration, 63 Fed. Reg. 8,477-04, 1998 WL 64863 (Dep't of Justice Feb. 19, 1998); Grider Drug No. 1 & Grider Drug No. 2, Decision & Order 77 Fed. Reg. 44,070-01 (Dep't of Justice July 26, 2012); The Medicine Dropper, Revocation of Registration, 76 Fed. Reg. 20,039-01 (Dep't of Justice Apr. 11, 2011); *Medicine Shoppe-Jonesborough*, Revocation of Registration 73 Fed. Reg. 363-01 (Dep't of Justice Jan. 2, 2008).

[237] *See* Thomas W. Prevoznik, *Birmingham Pharmacy Diversion Awareness Conference, DEA Perspective: Pharmaceutical Use & Abuse,* at 139-40 (Mar. 28-29, 2015), https://web.archive.org/web/20160418074249/https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2015/march_2015/prevoznik.pdf.

530. The framework of state and federal statutes and regulations, along with industry guidelines, make clear that pharmacies like those the PBM Defendants own are expected to use specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the abuse and diversion of prescription narcotics when dispensing of medications outside the usual course of professional practice.

531. Defendants were on notice that case law and administrative proceedings interpreting the CSA clearly required that their pharmacies must recognize and resolve all "red flags" indicating addiction, abuse and diversion, such as criminal, civil, or administrative actions pending against the prescriber, pattern prescribing, pharmacy shopping, doctor shipping, high abuse potential prescriptions, drug cocktails, *etc.* [238]

532. It is not just the single red flags that make the suspicious prescriptions unresolvable, but frequently the fact that there are multiple red flags at one time. So, rather than just looking for unresolvable single red flags, Defendants should have

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[238] *Holiday v. Holder*, 839 F. Supp. 2d 145; *Pharmacy Drs. Enterprises, Inc. v. Drug Enf't Admin.*, 789 Fed. App'x 724, 730 (11th Cir. 2019); *Holiday CVS*, 77 Fed. Reg. at 62,318, 62,326, 62,331, 62,344; *East Main Street Pharmacy*, 75 Fed. Reg. at 66,159; *Oak Hill Hometown Pharmacy v Dhillon*, 418 F. Supp. 3d. 124, 131 (S.D.W.Va., 2019); *Jones Total Health Care Pharmacy, LLC v. DEA*, 881 F.3d 823, 828 (11th Cir. 2018); "Centers for Disease Control, CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016," 65 Morb. And Mort. Wkly Rep. (Mar. 18, 2016) https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf; *See supra,* Prevoznik, *Birmingham Pharmacy Diversion Awareness Conference,* at 139-140, https://web.archive.org/web/20160418074249/https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2015/march_2015/prevoznik.pdf.

been looking for instances when there are multiple red flags in combination, which would make these truly unresolvable. According to *Holiday CVS*:

> Professor Doering specifically identified such red flags as. . . ; the respective locations of the patient and the prescriber . . . ; that a prescriber writes for certain combinations or patterns of drugs. . . .; and multiple patients presenting "prescriptions for the same drugs, the same quantities . . . from the same doctor without any kind of variability or change considering the different patients that come into the pharmacy," thus suggesting that the physician prescribes in a "factory like manner." *Id*. Professor Doering reviewed the various spreadsheets of the prescriptions dispensed by Respondents and testified regarding whether Respondents could have lawfully dispensed various prescriptions given the red flags they presented.[239]

533. Nor would Defendants be able to dispense a prescription with multiple red flags by simply making a call to the prescriber. According to *Holiday CVS*:

> Doering explained that the pharmacist examines multiple red flags collectively, and testified that, in his opinion, contacting the prescribing physician and/or obtaining a diagnosis code would not resolve these red flags to a degree where the medications should have been dispensed. Tr. 792–93. Doering agreed that he did not know what measures, if any, the Respondents' pharmacists took to resolve any conflicts, or whether a patient history screen was consulted prior to the dispensing event. Tr. 868, 873. When pressed on whether the distance red flags were potentially explainable under various hypothetical scenarios involving vacation and travel, Doering had this to say: "The kinds of medications that we're talking about here are for chronic health problems and not acute health problems. So, it would be unlikely that someone comes to Florida on vacation, breaks a leg, and has to get oxycodone in these quantities and in these strengths. So it just doesn't add up."[240]

534. At all times material hereto, Defendants have been in the position to recognize those red flags listed above. All or some of those red flags were frequently present in hundreds of thousands of prescriptions its pharmacies received during the

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[239] *Holiday CVS*, 77 Fed. Reg. at 62,318.

[240] *Id*. at 62,334.

relevant time period and should have caused the PBM Defendants' mail order pharmacies to refuse to fill prescriptions and/or report the behavior. However, Defendants failed to do so.

535. The PBM Defendants, as sophisticated owners of multiple mail order pharmacies, had the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores in diverse geographic locations. Each PBM, including Defendants, tracks every prescription claim it processes across all the health plans it services. Furthermore, Defendants could aggregate these data across various entities in the pharmaceutical supply chain, including drug manufacturer, pharmacies, insurers, and patients. Their own data would have allowed Defendants to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, and of prescribers or facilities that seem to engage in improper prescribing.[241]

536. Rather than use their data to limit problematic opioid utilization or investigate outlier prescribers, Defendants sold the data to third-party vendors who in turn resold the data to drug makers like Purdue Pharmaceuticals. Drug makers used these data to stoke increased sales of opioid drugs to physicians throughout America to treat the "fifth vital sign"—requiring healthcare providers to ask every patient about their pain, given the perception at the time that pain was undertreated.

[241] *See, e.g.*, *id.*, at 62,326-28 (DEA expert witness examined dispensing records alone to identify inappropriately dispensed medications).

Since that time, the U.S. has experienced a surge in opioid prescriptions—and, subsequently, an increase in overdoses and deaths tied to these painkillers.[242]

537. Yet, Defendants did little to leverage their resources and troves of information to stop or further question the wildly inappropriate prescriptions being written by prescribers until well after the opioid epidemic had reached its peak.

538. Defendants did little to fulfill their duties as the last line of defense and failed to ensure that the prescriptions they were filling were issued to legitimate patients for legitimate medical purposes by practitioners acting in the usual course of professional practice, as is evident by the copious amounts of opioids being dispensed by Defendants' mail order pharmacies throughout the United States.

539. The absence of controls against diversion is not surprising, given how the PBM Defendants' mail-order pharmacies operated to push virtually all prescriptions out the door, with little or no attempts at identifying or resolving red flags. The pressure on its pharmacists to fill large volumes of prescription made the performance of appropriate due diligence difficult, if not impossible.

540. For instance, employees at Express Scripts and Optum mail order pharmacies routinely complain of being under significant pressure to fill as many prescriptions as possible in as short amount of time as possible. In this vein, Express

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[242] Kristina Fiore, "Opioid Crisis: Scrap Pain as 5th Vital Sign? — Groups call on JC and CMS to re-evaluate policies that could lead to opioid overprescribing," *MedPage Today* (Apr. 31, 2016), https://www.medpagetoday.com/publichealthpolicy/publichealth/57336 [https://web.archive.org/web/20160415143337/https://www.medpagetoday.com/publichealthpolicy/publichealth/57336]

Scripts instituted a "point system" that governed the prescription-filling process in its mail order facilities. Under the point system, employees were awarded points for each prescription processed, and were given daily, weekly, or monthly point targets to reach. Employees would be able to leave early if a daily point threshold was reached and were penalized if specific point targets were not reached. Continuous point shortfalls would result in employees being placed on a "termination plan" or resulted in receiving other types of reprimands, up to and including termination.

541. This point system has acted as a carrot and stick for Express Scripts' pharmacists and technicians to fill as many opioid prescriptions as possible in as little time as possible, despite legal requirements to properly and adequately identify and resolve red flags.

542. Activities such as placing calls to physicians or patients to verify prescription information were also strictly monitored for timing and efficiency, which came at the expense of meeting industry safety standards. For prescriptions that required phone calls to verify certain information, Express Scripts required employees to make and complete 12 calls per hour (or 1 call every 5 minutes) to meet certain point goals. Employees who engaged in calls that exceeded acceptable time limits were often berated or penalized by management. Employees expressed feeling extreme pressure to fill prescriptions at all costs, which reflected Express Scripts' goal of trying to fill everything it could as quickly as possible.

543. Optum's mail order pharmacies had many of the same problems. Many pharmacists and technicians were fielding upwards of 100 calls a day regarding

things like prior authorizations. Even though not all calls dealt specifically with opioids, the sheer volume and pace of the calls hindered pharmacists' ability to vet each prescription carefully, as required by law.

544. Optum also required its prior authorization pharmacists to adhere to strict metrics concerning the number of cases per hour. The minimum number of cases to complete was set at seven cases per hour. This number of cases is unrealistic for a pharmacist to complete accurately and put undue pressure on pharmacists.

545. Optum prior authorization pharmacists described a pressure-filled environment to meet prior authorization quotas and address the queue of prior authorization requests. Prior authorization pharmacists were timed based on how many they reviewed per day and were ranked based on the number of requests they reviewed.

546. The pressure on mail order pharmacists was compounded by the constant threat of audits at Optum. Pharmacists were always under pressure because they were subjected to weekly audits to ensure they were meeting the required metrics. The audit would document not only total cases worked during the week, but there would be comments on mistakes, what cases were incorrect, or if any wrong decisions were made. The consequences of a bad audit often included termination for the pharmacist.

547. In 2017, OptumRx SVP David Calabrese emailed his colleagues that unless OptumRx addressed its mail-order opioid dispensing, "[w]e are only

contributing to the worsening of the problem."[243] He noted that OptumRx was dispensing "220K opioid Rx's out of our mail facilities annually at an average number of units per Rx of 187" and warned that "[w]e are talking out of both sides of our mouths if we allow this to continue as it is."[244] Calabrese wrote, "I strongly believe this needs Exec level attention."[245]

548. An OptumRx presentation from 2018 admits that it is a "[c]hallenge for individual rphs to identify controlled substance diversion in mail order setting," and that, prior to implementing a drug of concern review in 2018, OptumRx's pharmacists had "[n]o visibility of possible diversion indicators such as: Multiple patients with same shipping address [and] Multiple patients with same email address."[246] The document also acknowledged, "Due to lack of visibility diversion activity may occur repeatedly for an extended period of time."[247]

549. Given that Optum and Express Scripts' mail order dispensing policies prioritized speed and efficiency above all else, some employees reported complete mental and physical exhaustion, continuous fear of disciplinary action, and an unrelenting pressure to fill higher volumes of prescriptions in even shorter amounts of time.

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[243] OPTUMRX_JEFFCO_0000366858 (3/10/17).

[244] *Id.*

[245] *Id.*

[246] OPTUMRX_JEFFCO_0000385779 (7/11/18).

[247] *Id.*

550. Defendants' mail-order pharmacy entities were subject to DEA regulatory action for their failures to implement appropriate controls on dispensing. For instance, on May 15, 2012, Express Scripts Pharmacy Services, Inc. agreed to pay the United States $2.75 million to resolve allegations under the Controlled Substance Act. Among the allegations was that from 2002 through 2006, drug diversion occurred at several Express Scripts mail order facilities, including facilities in Bensalem, PA and Harrisburg, PA. Express Scripts experienced theft by employees of controlled substances, had inventory discrepancies, and failed to report in-transit losses to the DEA. According to the DOJ press release, from 2004 through 2009, Express Scripts employees utilized invalid DEA numbers in Express Scripts' computerized prescription processing system in order to process certain controlled substances prescriptions at all of its mail order facilities.

551. As part of the settlement, Express Scripts was required to develop a comprehensive Controlled Substances Security Compliance Plan that included diversion protection measures far beyond those required by law, including improved physical security, enhanced inventories, reconciliations and audits, employee background checks, and mandatory training for employees who have contact with controlled substances. Express Scripts executives, including the General Manager of Pharmacy Operations and the Chief Compliance Officer, were required to certify compliance with the terms of the Plan. In addition to the measures to protect against diversion of controlled substances, Express Scripts was also required to cease use of phony DEA numbers and agreed to set up an automated system to check the validity

of prescribers' DEA and NPI (National Physician Identifier) numbers against a national registry.

552. In addition, as discussed above, starting in the 1990s and continuing for decades, Express Scripts and/or its subsidiaries (e.g. Express Scripts Specialty Distribution Services, Inc.; Express Scripts SDS; HealthBridge, United BioSource LLC; Curascript) also worked as the administrator (e.g. processing applications, patient enrollment, patient approval, handling appeals, tracking and analyzing program data, adverse event reporting, etc.) and/or mail order pharmacy for manufacturers' opioid Patient Assistance Programs ("PAPs"), including for the troubled Purdue (Oxycontin, OxyIR) and Endo (Opana) PAPs. In connection with its PAP dispensing for Purdue and Endo, Express Scripts routinely violated the CSA by failing to ensure that only valid prescriptions were filled, failing to provide effective controls against diversion, and/or purporting to delegate its CSA responsibilities to the manufacturers funding the respective PAPs.

553. In connection with its opioid PAP and mail order dispensing and administration, Express Scripts routinely ignored clear indications of diversion, filled suspicious prescriptions, and/or improperly made opioid dispensing determinations at the direction of and/or with the inappropriate input/approval from the manufacturers funding the respective PAPs. The extent to which manufacturers controlled and/or had improper input into Express Scripts' dispensing practices is illustrated by the fact that the opioid PAP program created by Purdue and Express

Scripts allowed a single patient to receive an astonishing 360 tablets of OxyContin and 3,000 tablets of OxyIR a month.

554. Express Scripts' administration and improper dispensing practices relative to Purdue's and Endo's PAPs helped make the respective programs very successful marketing tools to increase opioid use, drive volume, and facilitate access to opioids including OxyContin, Opana, as well as other opioid products - resulting in Express Scripts filling 1 million+ opioid prescriptions and dispensing 100 million+ opioid pills throughout the country through these PAPs. As an illustration, in the early 2000s, Express Scripts was enrolling over 3,000 new patients per month for Purdue's PAP. Moreover, from at least the early 2000s, Express Scripts knew or should have known about the ongoing and growing misuse and diversion of opioids, and/or its opioid PAP work was causing opioid over-prescribing, over-dispensing, addiction and/or abuse, as well as the fact that it was a proximate cause of opioid diversion.

555. The Purdue and Endo PAPs and Express Scripts' administration and dispensing practices relative to same, raised numerous red flags, including dispensing large amounts of opioid to individuals, failing to conduct proper due diligence on patients, inappropriately recording deaths, and rerouting prescriptions to get around state laws.

556. For example, in 2010, Purdue audited Express Scripts' administration of this program and found numerous failures by Express Scripts to properly vet IPAP applicants, including failing to verify patient-doctor relationship, failing to notice

obvious inconsistencies in applications, and failing to process IRS information to determine accuracy and legitimacy of the information. In fact, Purdue found that during a period of just a few months in 2010 Express Scripts dispensed more than 17,000 OxyContin pills to fraudulent PAP enrollees/applicants. Similarly, a 2010 email exchange between Purdue and Express Scripts employees outlined how a Purdue PAP patient was reportedly "selling [his PAP opioid prescriptions] on the street."[248]

557. As a result of a whistleblower lawsuit brought by two former Las Vegas mail order pharmacists, in 2006 Medco agreed to a $155 million settlement to resolve claims with the United States related to its dispensing of drugs at its mail order pharmacies. The government's complaint alleged Medco accepted payments from drug makers to favor their drugs and submitted false claims for mail order prescription drugs provided to millions of federal employees, retirees and their families. Among the allegations was that Medco's mail order pharmacies failed to conduct adequate cDUR for all prescriptions in order to identify potential adverse drug interactions. The government alleged that, as a result of the pressures to meet quotas, Medco's cDUR employees regularly: a) fabricated physician call records so as to maintain hourly call quota rates; b) completed physician calls without ever having pharmacists verify the information with the physician's office; c) changed prescriptions without a pharmacist's intervention; and/or d) falsified records to

[248] PPLPC034000383800.

indicate cDUR calls were made to physicians when in fact these calls had not been made.

558. At all times material hereto, the PBM Defendants' mail order pharmacies have dispensed huge quantities of opioids. For example, during the 2006 to 2014 time period alone, Express Scripts and Optum pharmacies purchased more than 27 billion MMEs, spread over more than 1.4 billion dosage units according to the DEA's Automated Reports and Consolidated Ordering System ("ARCOS").

559. The DEA ARCOS database reveals that over 49% of the over 46 billion MMEs moved through the PBM mail order channel was purchased by Express Scripts pharmacies. Specifically, during the 2006 to 2014 time period, Express Scripts mail order pharmacies bought over 22.9 billion MMEs spread over 1.1 billion opioid dosage units.

560. Not surprisingly, given their lengthy collaboration with regard to OxyContin, over 26% of Express Scripts pharmacies' MME purchases were for Purdue opioids.

561. 23.63% of Express Scripts pharmacies' opioid purchases were for Teva opioids; 14.38% were for Mallinckrodt opioids; 8.34% were for Endo opioids; and 4.59% were for Mylan opioids. Express Scripts pharmacies dispensed these opioid products by mail to patients nationwide, including in Missouri and Plaintiff's Community.

562. The DEA ARCOS database also reveals that 9.6% of the over 46 billion mail-order MMEs were purchased by Optum's pharmacies. Specifically, during the

2006 to 2014 time period, Optum pharmacies bought and sold over 4.5 billion MMEs spread over 252 million opioid dosage units.

563. 21.75% of Optum's pharmacy opioid purchases were for Mallinckrodt opioids; 17.27% were for Teva opioids; 15.76% were for Purdue opioids; and 11.83% were for Endo opioids. Optum dispensed these opioid products by mail to patients nationwide, including in Missouri and Plaintiff's Community.

564. From at least 2008 to the present (and ongoing), Defendants violated the CSA, Missouri controlled substances laws (including the Missouri Comprehensive Drug Control Act), and the United States and state (including Missouri) pharmacy laws and regulations by dispensing controlled substances in violation of their corresponding responsibility under 21 C.F.R. § 1306.04(a) and outside the usual course of pharmacy practice under 21 C.F.R. § 1306.06.

565. Defendants violated the CSA, Missouri controlled substances laws (including the Missouri Comprehensive Drug Control Act), and the United States and state (including Missouri) pharmacy laws and regulations each time their mail order pharmacies filled a controlled substance prescription without identifying and resolving those red flags because, *inter alia*:

- They were knowingly filled outside the usual course of professional practice and not for a legitimate medical purpose; therefore, they were not pursuant to a valid prescription under 21 U.S.C. § 829 and thereby violated 21 U.S.C. § 842(a)(1); and

- They were knowingly and intentionally dispensed outside the usual course of professional pharmacy practice in violation of 21 C.F.R. 1306.06, and therefore such dispensing and delivering of controlled substances was not authorized by the CSA, and thereby violated 21 U.S.C. § 841(a)

566. The opioid crisis alleged herein is a direct and foreseeable result of Defendants' actions and inactions. And it was reasonably foreseeable that Plaintiff and Plaintiff's Community would be damaged thereby.

567. Defendants failed to maintain effective controls against abuse and diversion or conduct due diligence to ensure opioids were not diverted, resulting in the gross over-dispensing of opioids. Defendants thus directly contributed to today's opioid epidemic and corresponding harm to Plaintiff and Plaintiff's Community.

568. The opioid crisis alleged herein is a direct and foreseeable result of Defendants' actions and inactions. And it was foreseeable that Plaintiff and its community would be damaged thereby.

VII. Express Scripts and Optum Contributed to the Public Health Crisis in Lincoln County

569. By conspiring with and aiding and abetting the opioid manufacturers, facilitating the overprescribing and overuse of opioids, failing to address evidence of the misuse, abuse, and addiction to opioids, and failing to prevent diversion in their mail order dispensing and in their pharmacy networks, Optum and Express Scripts contributed to the oversupply of opioids in Missouri and Plaintiff's Community, and the resulting damages and public nuisance.

570. According to the CDC, the nation is experiencing an opioid-induced "public health epidemic." The CDC reports that over 1,000,000 people died from an overdose involving opioids from 1999 until present. Based on the latest data, approximately 3 million Americans met criteria for prescription opioid abuse and dependence in 2022. Since 1999, the amount of prescription opioids dispensed in the United States and the number of overdose deaths involving opioids have both quadrupled.

571. In addition to the toll on families and loved ones, opioid use imposes significant economy-wide costs. The U.S. Congress Joint Economic Committee estimates the opioid epidemic cost $1.04 trillion in 2018, $985 billion in 2019 and nearly $1.5 trillion in 2020 alone, up 37% from 2017 when the CDC last measured the cost. The rise in fatal opioid overdoses in 2022 suggests the total cost is likely to continue to increase.

572. As alleged previously herein, Missouri is experiencing a drug overdose epidemic which is causing devastating socio and economic consequences.

573. As alleged in detail above, Plaintiff has been particularly hard hit by the opioid epidemic that Defendants caused, contributed, and maintained.

574. As in many other communities in the United States, opioid use has been and continues to be at crisis levels in Missouri, including Lincoln County. Lincoln County has a population of approximately 54,800.

575. According to ARCOS data, between 2006 and 2019, Lincoln County was inundated with 28,489,767 dosage units of prescription opioids. That is enough for

each man, woman, and child in Lincoln County to have 36.9 doses of prescription opioids each year. In 2015, Missouri providers wrote 5.2 million prescriptions for opioids.

576. The Centers for Disease Control and Prevention has tracked prescription rates per county in the United States and calculated the geographic distribution at national, state and county levels of opioid prescriptions dispensed per 100 persons. This data shows that since at least 2006, the number of opioids dispensed per adult in Missouri has been higher than the national average.

577. According to data compiled by the CDC, between 2008 and 2018, the prescription rates in Lincoln County consistently exceeded the state and national prescription rates. For example, in 2008, the Lincoln County prescription rate of 87.1 per 100 persons was greater than the Missouri rate of 86.8 and the national rate of 78.2.

578. The Lincoln County prescription rate reached its peak in 2010 when 106.7 opioid prescriptions were dispensed for every 100 people, which was above both the Missouri prescription rate of 91.0, and the national average of 81.2 prescriptions per 100 people. The 2010 Lincoln County prescription rate was more than double the 2006 rate of 61.2 prescriptions per 100 people.

579. The Lincoln County prescription rates decreased from 66.1 in 2017 to 29.6 in 2019. In 2020, the Lincoln County prescription rate was 27.4.

580. As the volume of prescription opioids flooding into Lincoln County increased, Lincoln County experienced a marked increase over the past several years

on indicators related to opioid misuse, including number of deaths, emergency room use, and babies born with Neonatal Abstinence Syndrome (NAS).

581. The high dispensing rates in Missouri, including in Plaintiff's Community, have resulted in high numbers of overdose deaths. Overdose is the leading cause of death among adults 18-44 years old in Missouri. Between 1999 and 2015, Missouri experienced a 273 percent increase in the number of overdose deaths.

582. Between 2014 and 2019, an average of 1,344 Missouri residents died each year from drug overdoses. In 2020, 1,878 Missouri residents died from overdose, a 19% increase from 2019. In 2021, the number of overdose deaths rose to 2,155.

583. According to the Missouri Department of Health, over 70% of drug overdose deaths involve opioids.

584. Lincoln County's rate of opioid overdose deaths exceeded Missouri's rates. In 2013, Lincoln County had an opioid death rate of 12.99 per 100,000 compared to Missouri's rate of 10.4. In 2014, Lincoln County had a rate of 14.75 compared to Missouri's rate of 11.43. In 2015, Lincoln County's overdose rate of 20.11 – double the Missouri rate of 11.05. In 2016, the Lincoln County overdose rate of 19.90 exceeded the Missouri rate of 14.90. In 2017, the Lincoln County rate of 21.36 exceeded the Missouri rate of 15.56.

585. The Lincoln County injury rate for poisoning/overdose of 228.48 per 100,000 population was higher than the state rate of 203.09.

586. The loss of each of these individuals cannot be adequately conveyed by statistics, nor can the depth and breadth of the impact on those who survive.

587. Opioid overdose deaths are only one consequence of the opioid crisis. Opioid addiction also results in increased emergency room visits, inpatient hospitalizations, and emergency medical technicians' administration of naloxone, the antidote to opioids.

588. As a result of the increase in overdoses, the community has sustained high costs related to hospitalizations and first responders. According to data from the Missouri Foundation for Health, the total number of opioid-related hospitalizations and emergency department visits in Missouri increased by 138% between 2006 and 2015. In 2022, there were 4,147 emergency room visits in Missouri for non-fatal opioid overdoses.

589. In 2015, Lincoln County had 41 drug-related hospitalizations and 104 drug-related Emergency Department visits.

590. In 2020, 5,609 Missouri lives were saved with Naloxone.

591. Even infants and children have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. When untreated, NAS can be life-threatening.

592. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour. In Missouri, there was a 538 percent increase in babies born addicted to an opioid or other narcotic between 2006 and 2015. In addition, in 2018 substance use disorder was a contributing factor in 54% of pregnancy related maternal deaths in Missouri.

593. In 2011, Lincoln County had 5.52 per 1,000 births of children with NAS and by 2016, the rate was 36.29 per 1,000 births. Data from 2012 through 2016 reveals that Lincoln County's rate of NAS births and discharges per 1,000 live births exceeded the Missouri rate.

594. Hospital costs for NAS have grown more than six times since 2004.

595. The oversupply of opioids has also had a significant detrimental impact on children. Prescription opioid use before high school graduation is related to a 33% increase in the risk of later opioid misuse.

596. Between 2006 and 2010, Lincoln County had a substance abuse hospitalization of children (ages 1-19) rate of 15.1 per 100,000. Between 2011 and 2015, this rate increased to 19.1. The 2018 Missouri Kids Count Data found 135 emergency room visits for children under the age of 19 for alcohol and substance-related mental disorder.

597. The 2018 Lincoln County Behavioral Health Profile found, in a survey of children in grades 6-12, that the average age for the first misuse of over-the-counter and prescription drugs is ten years old. The survey also found that most youth get

prescription drugs from a friend or family member with pain medication being the most commonly misused prescription medication.

598. The Defendants' actions have also resulted in significant increases in crime and related criminal justice expenses. In 2017, there were 242 drug-related arrests in Lincoln County.

599. While Express Scripts and Optum were reaping millions of dollars in profits from their wrongful conduct, Plaintiff has been required to allocate substantial public monies and resources to combat the opioid crisis and cope with its fallout.

600. Plaintiff has incurred and continues to incur substantial costs because of Optum's and Express Scripts' conduct including, but not limited to, costs of increased services with respect to law enforcement and first responders; county health facilities, including clinics; detention centers and jails; county courts, including drug courts;; education programs;;; community outreach programs; equipment and supplies; victim services supports; drug abuse prevention and education programs; inmate services including housing, health and support staff; intervention programs; and increased costs associated with its own employee benefits plan, together with general societal and lost productivity costs and costs to repair and restore County infrastructure and services.

601. Plaintiff has had to allocate or re-allocate extraordinary resources through staffing at departments providing all of the services listed above; has incurred substantial increases in overtime and related costs associated with educational and judicial support services.

VIII. Facts Pertaining to the Formulary & UM Enterprise

602. As alleged above more fully *infra*, Express Scripts, Optum, both of their mail order pharmacies and each of the opioid manufacturers (including Allergan, Johnson & Johnson/Janssen, Endo, Insys, Mallinckrodt, Purdue, and Teva/Cephalon, referred to collectively as the "Opioid Enterprise Manufacturers" for the purposes of this Section) formed an association in fact enterprise, the "Formulary & UM Enterprise."

603. The Formulary & UM Enterprise was characterized by a common purpose, relationships among members of the Formulary & UM Enterprise, and sufficient longevity to accomplish the common purpose thereof. The PBM Defendants each conducted and participated in the conduct of the Formulary & UM Enterprise through a pattern of racketeering activity.

604. Each member of the Formulary & UM Enterprise knew that prescription opioids were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain. Each member of the Formulary & UM Enterprise was also aware that use of prescription opioids carried risks such as addiction, opioid use disorder, overdose, and death. Nevertheless, each member of the Formulary & UM Enterprise joined together into an association-in-fact enterprise for the common purpose of profiting from an expansion of the market for prescription opioids, and increased prescribing, dispensing, and sales of those drugs.

605. That each member of the Formulary & UM Enterprise is a for-profit company and may legally pursue profits is not in dispute. However, each member of

the Formulary & UM Enterprise sought to fulfill common purpose through a pattern of mail and wire fraud, and felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in controlled substances. Specifically, each member of the Formulary & UM Enterprise supported each other member in perpetrating a fraudulent scheme on the consumers who received prescriptions for prescription opioids, on the American public, and on the PBM Defendants' clients. Each member of the Formulary & UM Enterprise also supported each other member in feloniously possessing and dispensing controlled substances in Schedules II through IV in manners that were not authorized by the CSA.

606. Each member of the Formulary & UM Enterprise knew that prescription opioids were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain. Each member of the Formulary & UM Enterprise was also aware that use of prescription opioids carried risks such as addiction, opioid use disorder, overdose, and death. Therefore, each member of the Formulary & UM Enterprise knew that they needed to engage in a fraudulent scheme if they were going to increase the market for prescription opioids and increase their profits from prescribing, dispensing, and sales of prescription opioids.

607. For their part, the Opioid Enterprise Manufacturers" illegal marketing and false statements regarding prescription opioids have been well documented. They knew that prescriptions were dangerous and addictive and, nevertheless, marketed

them as safe and non-addictive. These representations furthered the common purpose of the Formulary & UM Enterprise.

608. The PBM Defendants, for their part, made representations alleged, *supra*, that their businesses were committed to making decisions about their formulary and UM offerings that were driven by a commitment to the health and safety of their covered lives and were focused on delivering safe healthcare.

609. PBM Defendants and opioid manufacturers also knew that the PBM Defendants' mail-order pharmacies were receiving prescriptions that were not for lawful orders of a practitioner. PBM Defendants and opioid manufacturers knew that the PBM Defendants' mail-order pharmacies were filling illegitimate prescriptions.

610. By these strategies, and the activities alleged *supra* and *infra*, both the PBM Defendants and the Opioid Enterprise Manufacturers agreed to further the common purpose of the Formulary & UM Enterprise through a fraudulent scheme and felonious possession and dispensing of controlled substances, and to grow the market for prescription opioids by increasing prescribing, dispensing, and sales of prescription opioids.

611. As an example, the Opioid Enterprise Manufacturers contracted and agreed with each PBM Defendant to coordinate unfettered formulary placement (with no or limited) UM measures regarding each opioid drug on the PBM Defendant's standard offerings, such that there would be as little impediment as possible to opioid prescribing and dispensing. From their agreements, each member of the Formulary & UM Enterprise stood to reap significant profits from ever-increasing prescribing,

dispensing, and sale of prescription opioids: the Opioid Enterprise Manufacturers from sales of their drugs and the PBM Defendants from rebates and other fees. As part of these agreements, the PBM Defendants gave each of the Opioid Enterprise Manufacturers parity terms, ensuring that no Opioid Enterprise Manufacturer's opioid was disadvantaged against within each class of opioid analgesics, and provided the Opioid Enterprise Manufacturers with data about the lives that they managed, the prescriptions written by doctors on their plans, and assistance with pull through contracts to assist them in pulling through the formulary decisions which would continue to increase prescribing and sales.

612. These contracts, and further information described below, evidence an agreement between the PBM Defendants, their mail-order pharmacies, and the Opioid Enterprise Manufacturers. Each PBM Defendant and each Opioid Enterprise Manufacturer understood that the PBM Defendants were going to operate on a fundamentally fraudulent basis. As alleged more fully *infra*, the PBM Defendants promised their clients they would take actions that would ensure that opioid prescribing and dispensing were safe and cost effective. The PBM Defendants also represented to legislative bodies and the public that their conduct was intended to maximize health, safety, and cost-effective healthcare for their covered lives. However, the PBM Defendants had agreed with each other and the Opioid Enterprise Manufacturers that their conduct would have the opposite effect. Instead of prioritizing health, safety, and cost-effectiveness, the Formulary & UM Enterprise and its members intended to obtain money and property from the prescribing,

dispensing, and sale of prescription opioids that they would not otherwise have received had they been honest and conducted their businesses along the lines of their public representations.

613. Importantly, some of the conduct alleged, above and below, may appear to be the behavior of competitors working against each other, or of opposing parties working to secure advantage at the expense of ether other. However, each PBM Defendant worked with each Opioid Enterprise Manufacturer in negotiations that were intended to maximize the amount of profit for the PBM Defendants and the Opioid Enterprise Manufacturers. As an example described earlier, discussion of formulary status and prior authorization were always a vehicle for discussion about the amount of rebates and administrative fees. As the Opioid Enterprise Manufacturers and PBM Defendants knew and intended, the end result was always the same—agreements for favorable formulary status without UM so that prescribing, dispensing, and sales could continue to increase.

614. The similarity of conduct by each PBM Defendant, including similar contract terms, pull-through marketing, facilitating dissemination of the Opioid Enterprise Manufacturers' marketing messages, favorable formulary status, as little UM as possible, research on behalf of the Opioid Enterprise Manufacturers, and free-flowing dispensing of prescription opioids, further evidences the existence of the Formulary & UM Enterprise. Each PBM Defendant knew of the other's conduct and refrained from commenting on or revealing the behavior, and continued to engage in

the same conduct so that all members of the Formulary & UM Enterprise could continue to profit from ever-increasing prescribing, dispensing, and sales.

615. That the PBM Defendants may have competed with each other for clients, or negotiated sharply with the Opioid Enterprise Manufacturers for increasing rebates and administrative fees did not undercut the common purpose of the Formulary & UM Enterprise because it did not slow or decrease the overall prescribing, dispensing, and sale of prescription opioids in the market as a whole. Similarly, competition among the Opioid Enterprise Manufacturers for increasing market share of their drug against a competitor's drug did not undercut the common purpose of the Formulary & UM Enterprise. For example, Purdue's competition with Endo for market share of OxyContin over Opana did not slow or decrease the prescribing, dispensing, or sale of prescription opioids as a class of drugs. Furthermore, each member of the Formulary & UM Enterprise knew that there would be competition in the market, but each member also knew that their participation in the Formulary & UM Enterprise was necessary to continue growing the market and agreed to work together towards that goal.

616. As alleged more fully herein, the Formulary & UM Enterprise caused direct injury to Plaintiff's money and property.

A. Formation of the Formulary & UM Enterprise

617. The Formulary & UM Enterprise was formed primarily in two ways, including: the forced dealing of the members with each other in the closed system of controlled substance manufacture, distribution, and dispensing, as well as the

members work together in trade associations and industry working groups like the PCMA and other informal groups described below.

618. First, the formation of the Formulary & UM Enterprise occurred, in part, through the parties' dealings with each other required by the closed system imposed by the CSA. The pharmaceutical industry is extremely insular and part of a "closed system" open only to those who register to do so. Other than their CSA obligations as mail order pharmacies, the PBM Defendants are some of the very few participants in controlled substance manufacturing, distribution and dispensing that are not required to register with the DEA. However, in their efforts to secure cost-effective access to controlled substances on behalf of their clients, the PBM Defendants were forced to work closely with the Opioid Enterprise Manufacturers.

619. Over at least the last two decades, the consolidation and acquisition of pharmacy benefit management companies into ever-larger entities has led to the formation of close personal business relationships between the few remaining PBMs and the Opioid Enterprise Manufacturers that were based on a shared interest in and the common purpose of ensuring the widespread dispensing of opioids.

620. There can be no doubt that the PBM Defendants and the Opioid Enterprise Manufacturers maintain interpersonal relationships with each other. As business entities, they have been negotiating with each other since the mid-1990s. And, as alleged above, the negotiations between the Opioid Enterprise Manufacturers and PBM Defendants often took place at, and/or involved, high level executives at both companies, a multitude of emails and phone calls, including personal calls

between executives to iron out details. The contractual dealings between the Opioid Enterprise Manufacturers and the PBM Defendants created relationships and provided context in which the common purpose of the Formulary & UM Enterprise could develop. Documents produced by the Opioid Enterprise Manufacturers and the PBM Defendants reveal that there have been decades of contract negotiations over rebate agreements, amendments, re-negotiations, payment discussions, and rebate invoicing. These contract negotiations were always geared towards maximizing the number of prescriptions written for the PBM Defendants' clients and ensure the most optimal formulary placement and least amount of UM under the PBM Defendants' standard offerings so that the prescribing, dispensing and sales could continue to grow.

621. The earliest indications of the existence of the Formulary & UM Enterprise can be found in the PBM Defendants' negotiations with Purdue, their work together on disseminating the Opioid Enterprise Manufacturers' marketing messages about prescription opioids, the presence of Purdue-paid speakers at the PBM Defendants' offices, and the PBM Defendants' research work supporting the Opioid Enterprise Manufacturers. Although the earliest indications of the Formulary & UM Enterprise's existence begin with Purdue and the predecessors of the PBM Defendants, the allegations above indicate that the Formulary & UM Enterprise grew to include all of the Opioid Enterprise Manufacturers and the consolidated PBMs now named as PBM Defendants.

622. As alleged more fully herein, various documents indicate that the Formulary & UM Enterprise found its beginnings with Purdue-sponsored doctors speaking at PBM offices, in the late 1990s, all across the country, and rebate contract negotiations between the Opioid Enterprise Manufacturers and the PBM Defendants that began around the same time and have continued through the present.

623. The formation of the Formulary & UM Enterprise did not happen solely within the formation of the rebate contracts between the Opioid Enterprise Manufacturers and the PBM Defendants. The Formulary & UM Enterprise also continued to develop through regular non-contractual interactions, including through the use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme in: (1) interactions about the administration of the rebate contracts; (2) pull-through marketing and assistance therewith; and (3) joint participation in trade associations and informal coalitions.

624. Trade associations and informal coalitions and forums not only provide a basis for the formation of the Formulary & UM Enterprise, but also serve as central conduits for the conduct of and participation in the Formulary & UM Enterprise.[249]

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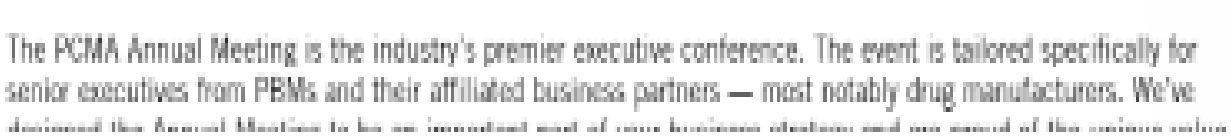
[249] *Pain Care Forum became 'echo chamber' for opiate distribution, epidemic in United States* (Sep. 19, 2016) https://www.oxfordeagle.com/2016/09/19/pain-care-forum-became-echo-chamber-for-opiate-distribution-in-united-states/; *see also,* Geoff Mulvihill, Liz Essley Whyte et al., "Purdue Pharma, Pain Care Forum fought opioid limit 'domino effect' Groups wage battle against Washington state's efforts to curb opioid overuse," *Times Union* (Sep. 18, 2016) https://www.timesunion.com/news/article/Purdue-Pharma-Pain-Care-Forum-fought-opioid-9229680.php; Matthew Perrone, "Painkiller politics: Effort to curb prescribing under fire," (Dec. 18, 2015) https://apnews.com/article/765439c771b649a7b6940fda87595735; Scott Higham,

The prime example of a trade association through which the Formulary & UM Enterprise developed and operated is the PBM's trade association, the Pharmaceutical Care Management Association ("PCMA").

625. PCMA describes itself as "lead[ing] the effort in promoting PBMs and the proven tools they utilize, which are recognized by consumers, employers, policymakers, and others as key drivers in lowering prescription drug costs and increasing access."[250]

626. While PCMA boasts of being the national association representing America's pharmacy benefit managers, it actually has a much broader membership base and focus. As evident from the PCMA website, PCMA membership includes member PBMs and so-called "Affiliate" drug manufacturers and other entities, including numerous of the Opioid Enterprise Manufacturers as current or former members.

627. As repeatedly mentioned in the PCMA's annual conference materials, the drug manufacturers are the PBMs' most notable business partners.[251]


The PCMA Annual Meeting is the industry's premier executive conference. The event is tailored specifically for senior executives from PBMs and their affiliated business partners — most notably drug manufacturers. We've

Sari Horwitz, Steven Rich and Meryl Kornfield, "Inside the Drive Industry's Plan to Defeat the DEA," *The Washington Post* (Sep. 13, 2019) https://www.washingtonpost.com/graphics/2019/investigations/drug-industry-plan-to-defeat-dea/.

[250] About PCMA, https://www.pcmanet.org/about/ (last visited Oct. 11, 2023).

[251] PCMA Annual Meeting 2016 Conference Program Book, https://www.pcmanet.org/events/past-events/2016-annual-meeting/ (last visited Dec. 5, 2023).

628. The PBM Defendants are members of PCMA, and due to their leadership positions, have substantial control over PCMA.[252] Indeed, PCMA is governed by PBM executives. The current board of PCMA includes Adam Kautzner, Pharm.D. (President of PBM Defendant Express Scripts); and Dr. Patrick Conway (CEO of PBM Defendant OptumRx).

629. An image illustrating the membership in the PCMA is as follows:[253]

630. Active control over the PCMA Board of Directors is important to the PBM Defendants and clearly conditioned on current employment by the PBM. As an

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[252] PCMA Board of Directors, https://www.pcmanet.org/board-of-directors/ (last visited Oct. 11, 2023).

[253] PCMA Annual Meeting 2016 Conference Program Book, https://www.pcmanet.org/events/past-events/2016-annual-meeting/ (last visited Dec. 5, 2023).

example, in 2022, former Express Scripts President Amy Bricker was the former Chair of the PCMA Board of Directors and the only Express Scripts employee on the Board. But, when Ms. Bricker left Express Scripts in late 2022/early 2023, she was removed from the PCMA Board. On February 3, 2023, PCMA issued a press release, naming Mr. Kautzner to the Board and as its Chair.

631. Each year during the relevant period, PCMA has regularly held industry conferences, including its Annual Meeting and Business Forum conferences.

632. Every year, high-level representatives and corporate officers from both the PBM Defendants and the Opioid Enterprise Manufacturers have attended these conferences to meet in person and engage in discussions, including those in furtherance of the Formulary & UM Enterprise.

633. In fact, many of the Opioid Enterprise Manufacturers have been "Partners," "Platinum Sponsors," or "Presidential Sponsors" of these PCMA conferences.

634. Notably, many of the forums at these conferences are specifically advertised as offering opportunities for private, non-public communications. For example, as Presidential Sponsors of these conferences, the Opioid Enterprise Manufacturers were permitted to host "private meeting rooms" that offer "excellent opportunities for interactions between PBM members, drug manufacturers, and other industry partners."[254]

[254] PCMA, *The PCMA Annual Meeting 2021 Will Take Place at the Broadmoor in Colorado Springs, CO September 20 and 21,* https://www.pcmanet.org/pcma-

635. Representatives from each PBM Defendant and the Opioid Enterprise Manufacturers have routinely met during the Annual Meetings and Business Forum conferences that PCMA holds (and the manufacturers sponsor) each year.

636. In addition, all PCMA members, including Affiliates and registered attendees of these conferences are invited to join PCMA-Connect, "an invitation-only LinkedIn Group and online networking community."[255]

637. As PCMA members and Affiliates, the PBM Defendants and the Opioid Enterprise Manufacturers utilized both PCMA-Connect, as well as the meetings facilitated by PCMA (including at conferences), to exchange information and to reach agreements in furtherance of the Formulary & UM Enterprise.

638. Thus, PCMA served as a conduit of information between the Opioid Enterprise Manufacturers and the PBM Defendants on subjects like access to prescription opioids.

639. That the PCMA served as a conduit for the sharing of information, and the formation of collaborative partnerships is not reasonably disputable. PCMA hosts regular meetings during which PBMs and Opioid Enterprise Manufacturers, or "Pharma" as they are called by the PBMs, can discuss their coordinated and shared objectives/strategies. PCMA's website posts programs for its regular meetings that

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event/annual-meeting-2021/ (an event "tailored specifically for senior executives from PBMs and their affiliated business partners" with "private reception rooms" and "interactions between PBM members, drug manufacturers, and other industry partners") (last visited Oct. 11, 2023).

[255] PCMA, *PCMA-Connect*, https://www.pcmanet.org/contact/pcma-connect/ (last visited Oct. 11, 2023).

highlight the close and "[i]mperative" collaboration and partnership between the PBMs and the Opioid Enterprise Manufacturers. Some examples from the program agendas and/or booklets currently available on PCMA's website include:

- Hot Topics and Trends Impacting Today's PBM and Pharma Strategies;
- Meeting Patients Where They Are: Pharma and PBMs working to close gaps in care in the post pandemic era;
- Unlocking the Value of PBM and Small Manufacturer Relationships;
- Manufacturers and PBMs Working Together to Reward Innovation;
- PBM & Pharma Priorities, Opportunities and Challenges in 2022 and Beyond;
- PBM and Pharma Collaboration: Focusing on Patients and Value;
- Collaboration Imperative—Identifying the Shared Interests of PBMs and Pharma;
- Market Dynamics Driving the PBM and Pharma Relationship;
- The Future of PBM-Pharma Relations and Negotiations;
- How Health Care Companies are Using Data and Predictive Algorithms to Identify and Address the Opioid Crisis;
- State of the PBM-Manufacturer Partnership;
- Confronting the Crisis We Brought Upon Ourselves: America's Opioid Abuse Epidemic;
- The PBM/Pharma Relationship in the Era of High Price Drugs; and
- PBMs, Specialty Pharmacies and Pharma Program Alignment—Affordability, Adherence and Outcomes.

640. Notably, PCMA only publishes the agendas and booklets from its regular meetings going back to 2014. Plaintiff is informed and believes that similar meetings would have been held, and topics discussed throughout the entirety of the relevant discovery period.

641. Given the foregoing, it is not surprising that Purdue viewed PCMA as a valuable source of information and coordination on subjects regarding prescription opioids and OxyContin. As examples, Purdue employees were notified about meetings at the PCMA conference in 2001 that discussed "oxy attacks as a predatory action on the part of the media or one of your competitors," and Burt Rosen (another Purdue employee) reached out to PCMA in 2014 to find the right person to connect with "on opioids."[256]

642. More broadly, produced documents show that PCMA (including through the regular use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme) served as a clearinghouse for communication, discussion, consensus building and speaking on behalf of the PBM Defendants and the Opioid Enterprise Manufacturers who were Affiliate members. Documents confirm that PCMA was a conduit through which discussions occurred and consensus could be reached (including discussion between the PBM Defendants outside of official PCMA correspondence) and that specific discussions and work took place around efforts to curb opioid abuse (which would have worked against the common purpose of the Formulary & UM Enterprise).

643. PCMA was not the only way in which the PBM Defendants and the Opioid Enterprise Manufacturers collaborated. Additional documents show that the members of the Formulary & UM Enterprise knew how to, and did form, ongoing informal coalitions that for years met regularly to work on issues of common concern

[256] PDD8801103934 (3/16/01); PPLPC018001107944 (10/2/14).

and advance their common interests. These documents show that a Controlled Substances Stakeholder's Coalition was formed in October 2013 in order to "further collaborate on interprofessional efforts to combat the United States opioid epidemic." At the time of the Coalition meeting in December 2016, these meetings had been ongoing for at least three years with each organization providing "updates for increasing awareness and decreasing misuse and diversion."[257]

644. Express Scripts claimed that it was making recommendations to physicians that had substantially decreased opioid prescriptions and taking actions to increase depository sites for drug disposal. As alleged more fully herein, however, documents confirm that Express Scripts and OptumRx were at the same time, in order to protect their shares of rebates and other fees, actively working with the Opioid Enterprise Manufacturers in the Formulary & UM Enterprise to avoid taking actions that would have reduced prescribing, thus ignoring their obligations to reduce unsafe and inappropriate prescribing.

645. Finally, documents will show that groups like PCMA supported the formation of the Formulary & UM Enterprise and agreements within it:

- "The Coalition discusses the terms 'drug abuse' and 'addiction' versus 'substance use disorder,' . . . and agreed";
- "Members then discussed the purpose of the slide deck . . . and agreed";
- "Additionally, the Coalition discussed various communication strategies . . . . Members agreed"; and

[257] *Id.*

- "Members unanimously agreed that further meetings were necessary to ensure that continued progress would be made."[258]

646. Members of the Formulary & UM Enterprise also participated in similar stakeholder meetings directly and/or through PCMA regarding topics like red flags and warning signs related to prescribing and dispensing controlled substances. The express purpose of these stakeholder meetings was to foster open channels of communication, foster understandings, and to discuss collaborative actions.[259] Notably, membership in some stakeholders meetings and working groups included some of the Opioid Enterprise Manufacturers' front groups and trade association (PhRMA), opioid distributors, the National Association of Chain Drug Stores, and other PBMs and pharmacies.

647. The foregoing facts, and as alleged in more detail herein, demonstrate that the Formulary & UM Enterprise arose from personal business relationships developed between the enterprise members in various ways over the course of at least the last two decades.

B. The Common Purpose and Fraudulent Scheme of the Formulary & UM Enterprise

648. The personal business relationships that formed the Formulary & UM Enterprise also allowed for the formation of a common purpose between the Opioid Enterprise Manufacturers and PBM Defendants in the Formulary & UM Enterprise.

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[258] *Id.*

[259] PPLPC019001069664 (11/14/2014); PPLPC019001069666 (11/14/2014); PPLPC019001100901 (2/26/2015); PPLPC019001100905 (2/26/2015); PPLPC019001100919 (2/26/2015); PPLPC019001100921 (2/26/2015).

Specifically, the Formulary & UM Enterprise was formed for the common purpose of illegally and fraudulently profiting from an expansion of the market for prescription opioids, and increased prescribing, dispensing, and sales of those drugs. As alleged more fully herein, the fraudulent scheme that furthered the common purpose of the Formulary & UM Enterprise relied on fraudulent representations from each PBM Defendant to each one of its clients and to the public that it would structure formulary offerings and perform cDUR benefit services in the interests of its clients and patients to ensure that opioids were prescribed and dispensed only for safe and legitimate reasons. Instead of providing standard formulary and UM offerings that were in their clients' best interests or for safe and legitimate reasons, the PBM Defendants made decisions that gave the Opioid Enterprise Manufacturers and their prescription opioids unfettered and preferred formulary access, without utilization management, and did not disadvantage any opioid compared with another in the same class or formulary tier, agreed to parity treatment for opioids within the same class and/or formulary, supported the Opioid Enterprise Manufacturers' pull-though marketing, pocketed enormous rebates and other fees, and (through its mail order pharmacies) dispensed prescription opioids without conducting the necessary due diligence.

649. Each member of the Formulary & UM Enterprise played a part and furthered the common purpose of the Formulary & UM Enterprise.

650. For their part, the Opioid Enterprise Manufacturers have been engaged in fraudulent conduct related to the marketing of prescription opioids beginning in the mid-1990s. As alleged by multiple entities and proven through extensive briefing,

the Opioid Enterprise Manufacturers engaged in a fraudulent scheme, including through the regular use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme, to grow the market for prescription opioids through the use of branded and unbranded marketing materials, key opinion leaders ("KOLs") to give speaker presentations and publish about prescription opioids, and front groups which would contribute to and publish books, articles, documents, etc., all of which misrepresented the benefits and risks of prescription opioid use.

651. The Opioid Enterprise Manufacturers commonly made the same misrepresentations through common KOLs and Front Groups. For example, each of the Opioid Enterprise Manufacturers made repeated misrepresentations about the risks and benefits of prescription opioids, including:

(a) The risk of addiction from chronic opioid therapy is low;

(b) To the extent there is a risk of addiction, it can be easily identified and managed;

(c) Signs of addictive behavior are "pseudoaddiction," requiring more opioids;

(d) Opioid withdrawal can be avoided by tapering;

(e) Opioid doses can be increased without limit;

(f) Long-term opioid use improves functioning;

(g) Alternative forms of pain relief pose greater risks than opioids;

(h) OxyContin provides twelve hours of pain relief; and

(i) New formulations of certain opioids, labeled abuse deterrent, successfully deter abuse.

652. Each of the Opioid Enterprise Manufacturers made nearly identical representations about their branded drugs and/or unbranded prescription opioids as a class of drugs during the relevant time period.

653. Each of the Opioid Enterprise Manufacturers used similar Front Groups to promote prescription opioid use. As examples, multiple of the Opioid Enterprise Manufacturers used Front Groups including, as examples, the following: the American Pain Foundation, the American Academy of Pain Medicine, the American Pain Society, Federation of State Medical Boards, the Alliance for Patient Access, the United States Pain Foundation, the American Geriatric Society, and the National Initiative on Pain Control.

654. The Opioid Enterprise Manufacturers took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that the Opioid Enterprise Manufacturers were consistently in control of their content and that it stayed on message in favor of more opioid prescribing. The Opioid Enterprise Manufacturers exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and, through the Front Groups, with each other to deceptively promote the use of prescription opioids.

655. Each of the Opioid Enterprise Manufacturers used similar Key Opinion Leaders and the strategy of paying opinion leaders and speakers who favored aggressive treatment of pain with prescription opioids. Pro-opioid doctors have been at the hub of the Opioid Enterprise Manufacturers' well-funded, pervasive marketing

scheme since its inception and were used to create the grave misperception that opioids were safe and efficacious. As examples, multiple Opioid Enterprise Manufacturers used similar Key Opinion Leaders including, but not limited to: Dr. Russell Portenoy, Dr. Lynn Webster, Dr. Perry Fine, and Dr. Scott Fishman.

656. Each of these Key Opinion Leaders and numerous other, lower profile doctors, were paid to speak on behalf of prescription opioids as an unbranded class of drugs. They were used extensively to present the appearance that unbiased and reliable medical research supported the broad use of prescription opioids. These pro-opioid doctors also began to write, consult on, edit, and lend their names to books and articles, they gave speeches, they served on committees, etc., all the while encouraging the use of prescription opioids.

657. The Opioid Enterprise Manufacturers' marketing conduct did not end with the KOLs and Front Groups—they were merely one of the vehicles for the dissemination of the misrepresentations. The Opioid Enterprise Manufacturers also used branded and unbranded advertising and marketing; funded, edited and distributed pro-opioid publications; speakers bureaus and continuing education programs. Examples of speakers bureaus and continuing medical education events occurring at the PBM Defendants' facilities are found throughout document productions from the Opioid Enterprise Manufacturers.[260] Furthermore, as alleged

[260] Purdue-produced documents 7003172769 (Merck Medco Speaker Program Dallas approved by Purdue 4/27/01); 7003178877 (United Healthcare-St Louis speaker program approved by Purdue 3/11/01); 7003178881 (related, 5/22/01); 7003178889 (United Healthcare of Rhode Island speaker program approved by Purdue on

above, the PBM Defendants often facilitated and/or disseminated the Opioid Enterprise Manufacturers' marketing messages directly to doctors who prescribed for patients covered by the PBM Defendants' clients.

658. One of the primary means by which the Opioid Enterprise Manufacturers disseminated their messaging about prescription opioids was through drug detailing: the practice of sending out pharmaceutical company representatives to provide details about specific branded products in order to persuade prescribers to begin writing (or write more) prescriptions for a specific product.

659. The Opioid Enterprise Manufacturers adopted detailing as a key component of their prescription opioids strategy early on to capitalize on the fraudulent unbranded marketing—developing carefully crafted marketing messages and tactics to deliver messages to prescribers through close relationships with sales representatives.

660. Drug detailing is data driven, requiring identification of the prescribers who are writing high or low volumes of prescriptions, targeting places where additional messaging might be affecting and to test the effectiveness of messaging. In accordance with common industry practice, the Opioid Enterprise Manufacturers purchased and closely analyzed prescription sales data from companies like IMS

3/30/01); 7006607303 (Merck-Medco speaker program to occur in Columbus, OH approved by Purdue on 9/10/99); 7006622039 (Merck-Medco speaker approval in New York approved by Purdue on 2/22/11); 7007850486 (Merck-Medco speaker approval in Mechanicsburg, PA approved by Purdue on 4/6/99).

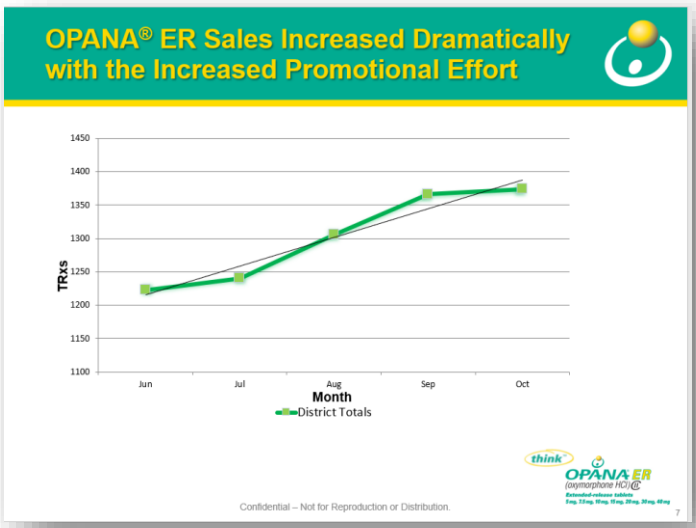
Health (now IQVIA) and the PBM Defendants which allowed them to track—precisely—the rates of initial and renewal prescribing by individual prescribers.

661. The nexus between data and detailing helped drive the formation of the common purpose of the Formulary & UM Enterprise. In return for data and unfettered formulary placement from the PBM Defendants, the Opioid Enterprise Manufacturers were willing to pay higher rebates and other fees to each PBM Defendant.

662. Once that occurred, the PBM Defendants once again supported the Opioid Enterprise Manufacturers' fraudulent marketing regarding prescription opioids. After the Opioid Enterprise Manufacturers obtained the PBM Defendants' data and favorable formulary placement, the Opioid Enterprise Manufacturers' sales personnel immediately began to analyze their managed care or PBM data in order to "pull through" the formulary placement in order to drive increased sales. Documents produced from the Opioid Enterprise Manufacturers and PBM Defendants are replete with examples of pull-through initiatives touting the beneficial formulary placement of Opioid Enterprise Manufacturers' drugs to drive increased sales and use of the PBM Defendants' data to maximize the pull through effort.

663. These documents make clear that the formulary placement was viewed as a "win" and an opportunity to make the rebate agreements profitable by pulling through sales. Sophisticated presentations outlining the exact steps a sales representative should take were often included in the sales training materials. The

impact of these agreements and the ability to pull-through increased sales using the PBM data was dramatic:



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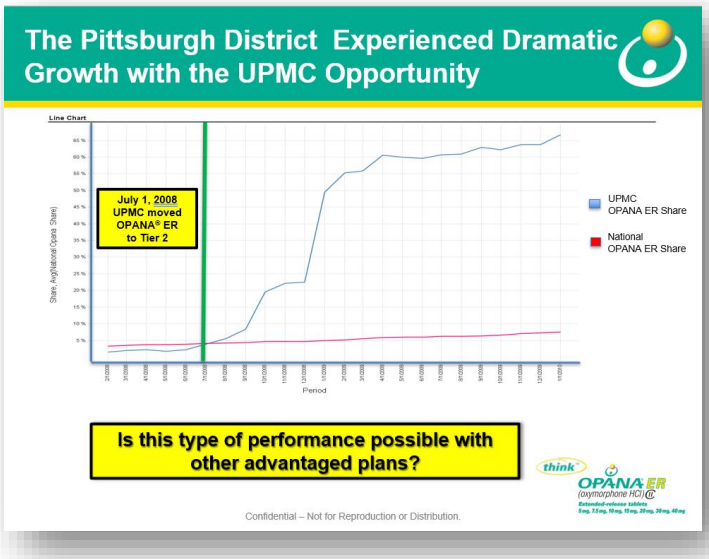
664. Using the "Best Practices Identified" of: 1. Identifying the local UHC MC Opportunity; 2. Targeting the Right UHC Customer; 3. Hyper Targeting; 4. Delivering the Right Message; and 5. Consistent Cross-Functional Communication[262] – the Pittsburgh District experienced dramatic growth in sales, as described by Endo:

[261] ENDO-CHI_LIT-00046379, slide 7.

[262] *Id.* at slide 10.



263

665. Formulary wins were a boon for each member of the Formulary & UM Enterprise. Each prescription opioid that enjoyed a favorable formulary placement, or continued to enjoy prescribing and dispensing without UM, ensured that all prescription opioids would continue to enjoy unrestricted sales due to the privity clauses that the PBM Defendants agreed to with each Opioid Enterprise Manufacturers. And, as indicated by the graph cited above, these wins increased sale. And, by increasing sales, the wins increased profits for the Opioid Enterprise Manufacturers whose drugs were sold and for the PBM who received rebates and administrative fees tied to sales. From that perspective, the graph above is literally evidence of the Formulary & UM Enterprise and its common purpose.

666. As alleged in more detail herein, the PBM Defendants took on obligations to perform and made representations that they would conduct point-of-

263 *Id.* at slide 9.

sale review, and take actions to ensure that only safe and legitimate prescriptions were being filled when they had no intention of doing so. Had the PBM Defendants taken the actions they had promised their clients, it would have dramatically reduced medically inappropriate prescribing, sales and dispensing of prescription opioids. As alleged more fully herein, the PBM Defendants' failure to do so had a significant role in allowing opioids to flood into communities across America, including into Plaintiff's Community.

667. The PBM Defendants also paid lip service to their commitment to taking action about prescription opioids. For example, Express Scripts represented in 2013 that it was "leading the fight against prescription drug fraud, waste and abuse."[264] Optum submitted its opioid use/risk management plan for consideration by the National Alliance of Healthcare Purchaser Coalitions, claiming that its program focuses on preventing misuse by educating care providers and consumers, minimizing early exposure and promoting alternative treatments for pain while advancing best practices and made multiple representations about itself and its programs during the presentation. Similar representations were made on OptumRx's website, touting its expertise and commitment to fight the opioid epidemic and demonstrating expertise in opioid management: "Optum Rx® implements a multi-dimensional Opioid Risk

[264] PPLPC019000862211 (11/18/13).

Management solution to help curb the rising tide of opioid abuse across the United States . . . as part of its commitment to drive opioid safety and prevention."[265]

668. But the PBM Defendants' claims that they were addressing fraud, waste, and abuse were only empty promises. For example, one former Fraud, Waste and Abuse investigator for Express Scripts from 2013 to 2019, Confidential Informant No. 1 (CI-1), explained that even when they identified blatant instances of pill seekers and pill mill doctors, nothing happened. "No one really cared," he said. "No one really followed up on anything. The members were just like a number. We'd totally forget this was a human being because it was just a case number. We'd just look at it, type it up and it was gone. They never got the help they needed. I never heard this person is in rehab."

669. Moreover, as far as CI-1 knew, none of his findings were ever shared with law enforcement, even if it involved well documented pill mill doctors or pill seekers.

670. CI-1 explained that, when he was hired, he thought he would be investigating "serious major fraud, all of these people writing all of these false prescriptions," he said. "I just thought it was more investigation stuff." They would re-run patients and doctors' names every five months, he said. "We'd see the same people over and over," he said. "Just because we identified the behavior didn't mean it stopped. We'd just call the doctors and they didn't even care. They just felt this

[265] Optum, "White Paper: Working to end the opioid epidemic" at. 7 (2018) https://www.optum.com/content/dam/optum3/optum/en/resources/white-papers/opioid-whitepaper-wf914999.pdf (last visited Oct. 11, 2023).

patient was in pain, but we're not going to do anything about it. It wouldn't be rare to have [the bad doctors] written up twice in a year. . . . I'd say 90 percent of the reports never got read in my opinion. . . . Let's say I spent months, sometimes weeks on a report—it's being written for the manager. It really doesn't go anywhere else."

671. Similarly, PCMA and some of its PBM members participated in coalitions or external activities indicating that they were "increasing awareness and decreasing misuse."[266] However, the internal documents produced by the PBM Defendants show a different story and uncover the fraudulent nature of the PBM Enterprises. The PBM Defendants did not make decisions based on the terms of the contracts with their clients or in order to fight drug abuse and/or diversion. Rather, the PBM Defendants made decisions in order to protect their rebates and generate profit, despite concerns about prescription opioids and the companies that sold them.

672. The PBM Defendants hid these facts from their clients. In a telling exchange in 2002, when Highmark Blue Cross Blue Shield decided it would put a 300mg daily limit on a drug, Medco pushed back because this meant that Medco would lose Purdue rebates if there was a limit below 320mg per day. Here, as alleged, was evidence that an action could have been taken to drastically limit inappropriate prescribing, sales and dispensing, but it was ignored in favor of the action that advanced the common purpose of the Formulary & UM Enterprise. Instead of taking action to limit medically unnecessary and inappropriate prescribing, sales and

[266] CAH_MDL2804_01524873 (12/15/16) (also indicating that Express Scripts had "[d]eveloped a matrix for making recommendations).

dispensing, an August 18, 2002, email from Purdue National Account Director Bernadette Katsur reveals that a Medco Vice President convinced its client—Highmark—to drop its daily dosage limit.

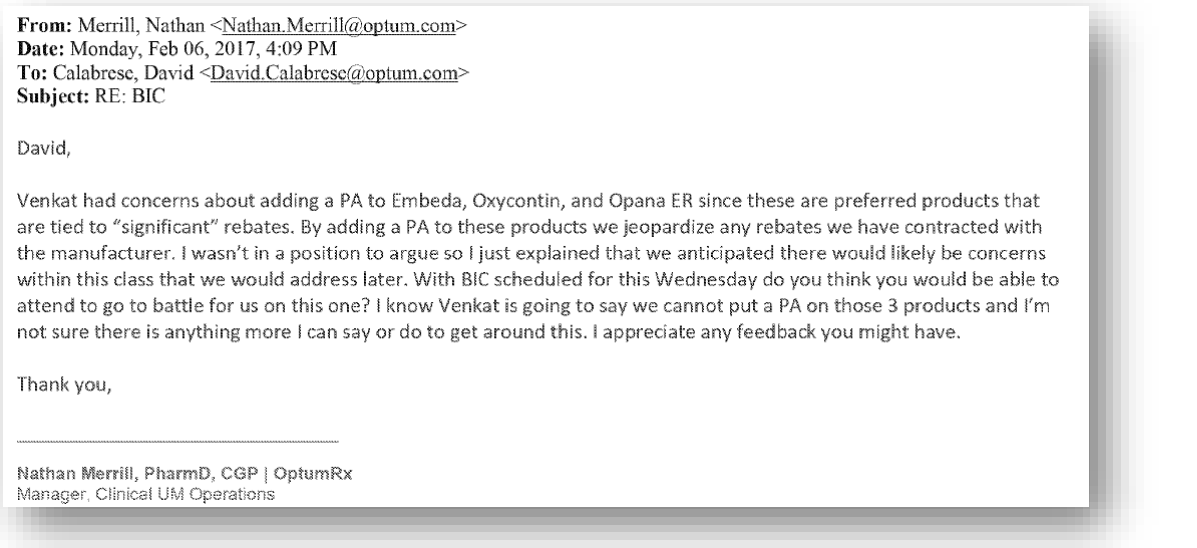
673. Documents created in the mid-2010s confirm that the PBM Defendants regularly delayed taking actions that could have dramatically reduced medically inappropriate prescribing, sales and dispensing despite promises from the PBM Defendants to do the same.

674. As an example, a November 3, 2016, email from Bob Lahman, Trade Relations VP at OptumRx explained that OptumRx had agreed to forego measures that would have used prior authorization as a tool to control the prescription of opioids. The explanation reveals how closely each Opioid Enterprise Manufacturer worked with each PBM Defendant: "It was not unusual for any manufacturer to not want a PA on their product, especially if it was a small molecule product, and very few would have agreed to a rebate where they did not have unrestricted access (no PAs or steps (sic) edits)."[267] Emails like this, and others cited throughout this complaint, demonstrate that the PBM Defendants and the Opioid Enterprise Manufacturers all had an understanding of the game—the end goal was increasing prescribing, dispensing, and sales through favorable formulary access without UM, and the means to that end goal was pay rebates and administrative fees.

675. When the pressure began mounting to limit access to prescription opioids by use of UM measures like prior authorization, step edit, or days' supply

[267] OPTUMRX_JEFFCO_0000446761 (11/3/16).

limits, there were serious concerns expressed in 2017 within OptumRx about the impact on the "significant" rebates being received from the drug makers:



From: Merrill, Nathan <Nathan.Merrill@optum.com>
Date: Monday, Feb 06, 2017, 4:09 PM
To: Calabrese, David <David.Calabrese@optum.com>
Subject: RE: BIC

David,

Venkat had concerns about adding a PA to Embeda, Oxycontin, and Opana ER since these are preferred products that are tied to "significant" rebates. By adding a PA to these products we jeopardize any rebates we have contracted with the manufacturer. I wasn't in a position to argue so I just explained that we anticipated there would likely be concerns within this class that we would address later. With BIC scheduled for this Wednesday do you think you would be able to attend to go to battle for us on this one? I know Venkat is going to say we cannot put a PA on those 3 products and I'm not sure there is anything more I can say or do to get around this. I appreciate any feedback you might have.

Thank you,

Nathan Merrill, PharmD, CGP | OptumRx
Manager, Clinical UM Operations

[268]

676. Later, OptumRx employees discussed whether they would be willing to put a hard limit on morphine equivalent dosing (MED) on OxyContin 80mg to align with the 2016 CDC Prescribing Guidelines. The discussion was immediately interrupted by Brian Sabin, Manager of Industry Relations, who explained that they needed to delay implementation to "ensure we protect rebates" because "we cannot sacrifice rebates on only the 80mg strength here" as that would mean OptumRx would "sacrifice rebates on *all* OxyContin scripts."[269]

[268] OPTUMRX_JEFFCO_0000206377. (2/7/17).

[269] OPTUMRX_JEFFCO_0000261777 (6/9/17).

Based solely on the Purdue contract, **I would highly suggest delaying the MED implementation on all clients until 1/1/2018** – as we are doing with the new criteria – so we have time to ensure we can protect rebates. Purude has a clause built into their agreement that mandates that ALL strengths be unrestricted. So we cannot sacrifice rebates on only the 80mg strength here. We would sacrifice rebates on *all* Oxycontin scripts.

[270]

677. Here, again, a PBM Defendant did not take an action that it could have taken to block inappropriate prescription opioid dispensing.

678. As another example, despite their contractual obligations and their public representations, it was not until 2019 that OptumRx even began to consider exclusion of OxyContin from its formularies.

679. An email exchange in March 2019 between Brian Sabin, Optum Director of Industry Relations, and Venkat Vadlamudi, Optum, raises the question whether they should remove OxyContin from its formularies altogether, "rebate losses be damned," arguing that Purdue caused the opioid epidemic and Optum's continued inclusion of OxyContin on its formularies was "rewarding their bad behavior." He argues that, "[f]rom a purely PR perspective, I think it would look good on us." In response, Vadlamudi states that "[w]e as a company looked into this," but the amount of OxyContin rebates Optum collected "prevented us from doing it." As even Vadlamudi then goes on to admit, "[b]ut times are different now. [I]f you can look into it and model the scenarios maybe we can change."[271]

[270] *Id.*

[271] OPTUMRX_JEFFCO_0000506200 (3/4/19).

680. Even as Purdue explored bankruptcy and OptumRx became aware of the potential for lost rebates, the answer was not to discontinue OxyContin's preferred formulary position, but instead to move other drugs into preferred positions in order to ensure the free flow of prescription opioids from another Opioid Enterprise Manufacturer in the Formulary & UM Enterprise.

681. Express Scripts went through similar issues with OxyContin prescribing. In a March 2017 email, there were several employees from Express Scripts who derided the decision by the Express Scripts Value Added Committee to overrule the prior authorization limit on OxyContin, stating that the decision did not sit well with them at all. As Express Scripts employees noted, this decision made no clinical sense. Without question, the prior authorization limit would have dramatically reduced medically inappropriate prescribing, sales, and dispensing which would have impacted "rebate gain."

682. But the PBM Defendants' involvement did not end there. As alleged more fully herein, Express Scripts and Optum each own and operate a mail order pharmacy. As alleged above, each of the PBM Defendants' mail order pharmacies dispensed massive amounts of branded and generic opioids without performing the requisite due diligence on prescriptions or refusing to fill prescriptions that could not be resolved through due diligence. As such, the mail order pharmacies provided another mechanism for the goal of the Formulary & UM Enterprise—*i.e.*, the unrestricted increase in prescribing and dispensing of prescription opioids for the profit of the Opioid Enterprise Manufacturers and the PBM Defendants.

683. By dispensing branded and generic prescription opioids without performing the requisite due diligence on prescriptions or refusing to fill prescriptions that could not be resolved through due diligence, the PBM Defendants' mail-order pharmacies furthered the common purpose of the Formulary & UM Enterprise. They continued to facilitate the increased dispensing and sale of prescriptions opioids. However, this also violated the law governing dispensing controlled substances in Schedules II through IV in ways that are punishable as felonies.

684. As alleged more fully herein, the Formulary & UM Enterprise maintained a common purpose from the late 1990s through to the present day, creating sufficient longevity in their personal business relationships for them to pursue the common purpose of the Formulary & UM Enterprise.

C. Conduct and Participation of the Formulary & UM Enterprise Through a Pattern of Racketeering Activity

685. The common purpose of the Formulary & UM Enterprise alleged more fully herein was perpetrated through a fraudulent scheme fulfilled by multiple acts of mail fraud and wire fraud, and by felonious possession and dispensing of controlled substances. PBM Defendants predicate acts of racketeering constituting a pattern of racketing activity.

686. The pattern of racketeering activity used by the PBM Defendants and their mail order pharmacies likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme through which the common purpose was achieved.

687. Use of the mail and wire facilities began with the formation of the Formulary & UM Enterprise. Negotiations and communications about the contracts between the PBM Defendants and the Opioid Enterprise Manufacturers occurred through interstate mail and wire facilities and involved meetings, communications, and negotiations about contracts between the PBM Defendants and the Opioid Enterprise Manufacturers, the Opioid Enterprise Manufacturers' marketing and the PBM Defendants assistance therewith, and pull-through marketing which required the transmission of large volumes of data.

688. As alleged more fully herein, the Opioid Enterprise Manufacturers and the PBM Defendants regularly and continuously communicated through the use of the U.S. Mail and interstate wire facilities in furtherance of the common purpose of the Formulary & UM Enterprise and their fraudulent scheme, including discussions of formulary placement, prior authorization limits, step edits, preferred formulary status and their impact on opioid prescribing and dispensing and, relatedly, rebates and other fees. Importantly, rarely mentioned during these discussions was the impact of the burgeoning opioid epidemic. These discussions were clearly intended to further the common purpose of the Formulary & UM Enterprise, happened over at least the last two decades (beginning with Purdue's work with predecessors of Optum and Express Scripts and continuing to involve more Opioid Enterprise Manufacturers over time), and reveal the ongoing personal business relationships that developed between the members of the Formulary & UM Enterprise.

689. Similarly, each PBM Defendant engaged in significant pull-through marketing assistance with each Opioid Enterprise Manufacturer. As revealed by documents cited herein, each of the PBM Defendants, through the regular use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme, agreed to provide the Opioid Enterprise Manufacturers with preferred formulary placement and prescribing data. This ensured that the unfettered formulary access (granted despite the PBM Defendants' contrary representations to the public and their clients), would facilitate unrestricted opioid prescribing and dispensing. Documents confirm these facts and evidence that unrestricted formulary access was a boon for each Opioid Enterprise Manufacturers marketing efforts and that "pull through" efforts were undertaken after each formulary announcement "win" in order to drive the Opioid Enterprise Manufacturers' profitability. The PBM Defendants were not only aware of this pull through marketing, they actively joined in efforts with the Opioid Enterprise Manufacturers by creating reports about the "value proposition" of unrestricted use of prescription opioids as alleged more fully herein.

690. Finally, each PBM Defendant and the Opioid Enterprise Manufacturers regularly (and through the regular use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme) participated in trade industry associations and informal coalitions that provided recurring non-contractual opportunities and forums in which to continue developing personal business relations and in which they form a common purpose of growing the unfettered use of opioid drugs.

691. The PBM Defendants each engaged in essentially uniform conduct with the Opioid Enterprise Manufacturers whereby the PBM Defendants granted the Opioid Enterprise Manufacturers' drugs unfettered formulary access (including preferred formulary placement coupled with refraining from UM) despite their public promises and contractual obligations to make formulary and UM decisions in their clients' best interests, and facilitated their pull through marketing and/or directly facilitated the dissemination of their marketing messages. The PBM Defendants also provided the Opioid Enterprise Manufacturers with PBM data so that they could pull through the formulary "wins" and drive increased prescribing. At the back end of the fraudulent scheme, the PBM Defendants profited from their fraud by receiving rebates and other fees while the Opioid Enterprise Manufacturers enjoyed increased sales through pull through marketing and unfettered formulary access.

692. The fraudulent scheme was advanced through mailings and interstate wire transmissions that constitute racketeering activity. Collectively, these violations constitute a pattern of racketeering activity, through which the PBM Defendants and their mail order pharmacies and the Opioid Enterprise Manufacturers defrauded and intended to defraud consumers in Missouri and Plaintiff's Community, the State, and other intended victims.

693. The PBM Defendants and their mail order pharmacies devised and knowingly carried out an illegal and fraudulent scheme using materially false or fraudulent pretenses, representations, promises, or omissions regarding their conduct. Specifically, as alleged more fully herein, the PBM Defendants promised to

perform pharmacy benefit management services, including cDURs, formulary decisions, and UM decisions in their clients' best interests and in ways that would ensure safe and effective prescribing. As alleged herein, the PBM Defendants further represented to their clients and the public that they were committed to preventing and addressing misuse, abuse, and diversion of prescription opioids. These promises were made in person, in publications, and through the mail and the wires.

694. The PBM Defendants and their mail order pharmacies did not intend to comply with their contractual obligations, the promises to their clients, or their public representations. The PBM Defendants and their mail order pharmacies intended to continue to make decisions and take actions that benefitted the members of the Formulary & UM Enterprise and its common purpose by: failing to perform cDURs, granting unfettered formulary access, and blocking implementation of any UM measures. All told, the PBM Defendants and their mail order pharmacies intended to take actions that directly contradicted their promises, contractual obligations and public promises because they supported increased prescribing, sale, and dispensing of prescription opioids with as little inhibition or impediments as possible.

695. The PBM Defendants and their mail order pharmacies intended that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities intentionally and knowingly with the specific intent to advance and for the purpose of executing the illegal and fraudulent scheme.

696. By engaging in their intended conduct, as alleged more fully herein, the PBM Defendants and their mail order pharmacies engaged in fraudulent and unlawful conduct constituting a pattern of racketeering activity.

697. The PBM Defendants and their mail order pharmacies used the U.S. Mail and interstate wire facilities to perpetrate the fraudulent scheme of the Formulary & UM Enterprise with thousands of communications, publications, representations, statements, electronic transmissions, and payments including, but not limited to:

(a) Contracts negotiated and circulated between members of the Formulary & UM Enterprise;

(b) Contracts negotiated and circulated between PBM Defendants and their clients;

(c) Public representations by the Opioid Enterprise Manufacturers and the PBM Defendants about their commitment to addressing misuse, abuse, and diversion of prescription opioids;

(d) Marketing materials about prescription opioids transmitted between the Opioid Enterprise Manufacturers and the PBM Defendants that were later disseminated by the PBM Defendants;

(e) Communications between the PBM Defendants and their clients about their commitment to following the terms of their respective contracts;

(f) Communications between the Opioid Enterprise Manufacturers and the PBM Defendants regarding formulary changes;

(g) Communications between the Opioid Enterprise Manufacturers and the PBM Defendants regarding and including PBM prescribing data;

(h) Transmission of rebate payments; and

(i) Transmission of payments from the clients of the PBM Defendants.

698. To achieve the common purpose of the Formulary & UM Enterprise, the PBM Defendants and their mail order pharmacies and the Opioid Enterprise Manufacturers hid from their clients, patients, regulators and Plaintiff: (a) the fraudulent nature of the scheme; (b) the fraudulent nature of their representations; (c) their intention to ignore their contractual cDUR obligations; (d) intent to make formulary and UM decisions that failed to limit the medically unnecessary and inappropriate prescribing, sales, or dispensing of prescription opioids or address misuse, abuse, and diversion; and (e) the true nature of the association between each member of the Formulary & UM Enterprise.

699. Each member of the Formulary & UM Enterprise, including the PBM Defendants and their mail order pharmacies, agreed with the overall objective of the Formulary & UM Enterprise's fraudulent schemes and participated by taking action that furthered the common purpose of the Formulary & UM Enterprise, including in the common course of conduct to commit acts of fraud and indecency.

700. The pattern of racketeering activity involving the felonious possession and dispensing of controlled substances in Schedules II through IV likely involved thousands, if not millions, if improperly dispensed prescriptions for branded and generic prescription opioids in violation of the CSA and PBM Defendants' registrations as mail-order pharmacies. PBM Defendants knowingly and intentional possessed and dispensed branded and generic prescription opioids for reasons that were not authorized by the CSA.

701. The predicate acts of the Formulary & UM Enterprise all had the purpose of furthering the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue for the PBM Defendants and their mail order pharmacies. The predicate acts were committed, and/or caused to be committed, by the PBM Defendants and their mail order pharmacies through their participation in the Formulary & UM Enterprise and in furtherance of their fraudulent schemes, felonious possession and dispensing of controlled substances, and common purpose thereof.

IX. Plaintiff's Claims Are Timely

702. Defendants' wrongful conduct is still ongoing and has caused Plaintiff repeated injuries and/or a continuous injury over many years.

703. A reasonably prudent person in Plaintiff's position would not have known, or been placed on inquiry notice, not just of the Defendants' wrongful conduct, but that substantial, non-transient damage had resulted and was capable of ascertainment. Mo. Ann. Stat. § 516.100. Plaintiff did not learn that it had been injured by Defendants' actions, the source of those injuries, or that those injuries were part of a pattern of conduct until only recently, until documents revealing those facts were produced in discovery by various entities in *In re: National Prescription Opiate Litigation*, Case No. 1:17-md-2804-DAP (N.D. Ohio) and other opioids litigation, including the documents cited, quoted, and relied on throughout this complaint. These documents—and the facts they contain—have never before been made public, nor have they ever before been in Plaintiff's possession, and not otherwise available to Plaintiff before being produced in discovery. Thus, any applicable limitations

period did not begin to run when Defendants committed their wrongful acts but when the damage resulting from Defendants' wrongful acts was sustained and capable of ascertainment by Plaintiff, which did not occur until the documents revealing those facts were produced in discovery.

704. Defendants are also equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiff and to purposefully conceal their unlawful conduct. Mo. Ann. Stat. § 516.280.

705. Defendants undertook efforts, including through the use of the U.S. Mail or interstate wire facilities in furtherance of the fraudulent scheme, to purposefully conceal their wrongful conduct by: (1) manipulating and distorting public information, knowledge, and facts; (2) misrepresenting their role in the pharmaceutical market as promoting safe use and appropriate opioid dispensing; (3) assuring the public and governmental authorities that they were complying with their obligations and were acting to prevent diversion and drug abuse; (4) hiding the true nature of their relationships with the Opioid Manufacturers; (5) failing to make public or otherwise produce nonpublic information, over which Defendants had exclusive possession, dominion, and control, that would have revealed the truth; (6) entering into overly broad confidentiality agreements with any entity in the supply chain with whom they contracted; (7) suing governmental and other entities to block the release of details in their agreements with the Opioid Manufacturers and pharmacies; and (8) by deliberately and fraudulently concealing the truth.

706. Defendants fraudulently concealed from Plaintiff the existence of Plaintiff's causes of action. Defendants' public misrepresentations about their role in the pharmaceutical market, and that they were ensuring the safe use and appropriate opioid dispensing, and preventing diversion and drug abuse, prevented Plaintiff from investigating Defendants' fraud.

707. Defendants also concealed from Plaintiff the existence of Plaintiff's claims by misrepresenting to the public, as well as to their clients, that they used their market power to create formularies and UM programs based on the health and safety of the public and of the lives covered by the benefit plans that were their clients. As alleged herein, Defendants repeatedly represented that they were working to ensure that opioids were prescribed and dispensed only for safe and legitimate reasons. These misrepresentations were made in person, in client contracts, on Defendants' websites, in publications and in Congressional testimony. Defendants told the public, their clients and Congress that they were experts who were committed to preventing and addressing misuse, abuse, and diversion of prescription opioids.

708. The PBM Defendants and their mail order pharmacies hid from their clients, patients, regulators and Plaintiff: (a) the fraudulent nature of their relationship with the Opioid Manufacturers; (b) the fraudulent nature of their representations; (c) their intention to ignore their contractual cDUR obligations; (d) intent to make formulary and Utilization Management decisions that failed to limit the medically unnecessary and inappropriate prescribing, sales, or dispensing of

prescription opioids or address misuse, abuse, and diversion; and (e) the true nature of the association between each member of each PBM Enterprise.

709. Plaintiff did not discover the nature, scope and magnitude of Defendants' misconduct, and its full impact on Plaintiff's Community, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

710. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff's Community. Plaintiff and Plaintiff's Community did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

711. Plaintiff and Plaintiff's Community reasonably relied on Defendants' affirmative statements alleged herein, including those regarding Defendants' commitment to preventing and addressing the misuse, abuse, and diversion of opioids.

X. Successor Liability

712. To the extent that the wrongful acts or omissions alleged herein where committed or omitted by predecessor entities, their respective successor entities are liable for those acts or omissions because (1) they expressly or impliedly assumed the predecessor's liability, (2) there was a consolidation or merger of predecessor and successor, (3) the surviving entity was a mere continuation of the predecessor or (4) when the transaction is entered into fraudulently to escape liability for the debts and liabilities. To the extent there was no formal merger of predecessor and successor, the respective successor entities are also liable for the wrongful acts or omissions of their respective predecessors based on the doctrine of de facto merger based on the

factors of (a) continuity of shareholders resulting from the purchasing corporation paying for the assets with shares of its own stock so the selling corporation stockholders become a constituent part of the purchasing corporation; (b) cessation of ordinary business and dissolution of the predecessor; (c) assumption by the successor of liabilities ordinarily necessary for the uninterrupted continuation of the business of the predecessor; and (d) continuity of management, personnel, and general business operation of the predecessor. The details regarding the foregoing facts are particularly within the knowledge and control of the respective defendants charged with wrongdoing and cannot be pleaded in greater detail by Plaintiff without discovery.

XI. Alter Ego Liability

713. To the extent that the wrongful acts or omissions alleged herein where committed or omitted by wholly-owned or majority-owned entities, the parent entities are liable for those acts or omissions as alter egos because (1) they dominated and controlled the wholly-owned or majority-owned entity and (2) exercised that domination and control to perpetrate a wrong or injustice. The details regarding the foregoing facts are particularly within the knowledge and control of the respective defendants charged with wrongdoing and cannot be pleaded in greater detail by Plaintiff without discovery.

XII. Claims for Relief

FIRST CLAIM FOR RELIEF—CREATION OF A PUBLIC NUISANCE (Brought by Plaintiff against All Defendants)

714. Plaintiff repeats, re-alleges, and incorporates each and every allegation set forth in all other paragraphs of these Supplemental and Amended Allegations to the Complaint, as well as each and every allegation set forth in all other paragraphs of its Complaint (Doc. No. 1), as if fully set forth herein, and further alleges as follows:

715. Defendants intentionally and/or negligently and recklessly caused, created, contributed to, and/or maintained a public nuisance which interfered with public rights, including the public rights to health and safety, in Plaintiff's Community.

716. Each Defendant is liable for the public nuisance because its conduct has caused an unreasonable and substantial interference with a right common to the general public, which is the proximate cause of, and/or substantial factor leading to, Plaintiff's injury. *See* Restatement Second, Torts §821B.

717. Defendants, by colluding with manufacturers to make opioids more available and ignoring evidence of addiction and misuse found in their own claims data and/or other actions and inactions described herein, created and maintained the opioid epidemic in Plaintiff's Community, which is harmful and disruptive to, and unreasonably annoys, injures, endangers, and interferes with the public health, public safety, public peace, public comfort, and/or public convenience. The public nuisance caused by Defendants has significantly harmed, and continues to

significantly harm, the Plaintiff and a considerable number of the residents of Plaintiff's Community.

718. Each Defendant gathered enormous amounts of data about the opioid prescriptions and opioid-related claims of their members in Plaintiff's Community and across the country. Defendants used this data to enhance their profitability but opted not to use it to inform their marketing practices, identify and prevent diversion, or identify and prevent the dispensing and sale of unreasonably large quantities of opioids, and "cocktails" of opioids and other drugs, in Plaintiff's Community and the surrounding communities.

719. Defendants have created and maintained a public nuisance through their ongoing intentional and/or negligent and reckless conduct, including, but not limited to: undertaking to administer prescription drug benefits and dispensing in the public interest and in conformity with public health and safety, and then electing not to (and/or failing to) appropriately carry out these obligations; fraudulently and/or falsely promoting the use of opioids for conditions and in circumstances where they are neither safe nor effective; misrepresenting to the public and the medical community that opioids could be taken at high does and for long durations with minimal risk of addiction; electing not to (and/or failing to) use the wealth of data available to them to identify and address signs of over-prescribing, illegitimate and dangerous use of opioids, misuse, abuse, and diversion; facilitating and encouraging the use of dangerously addictive opioids by colluding with manufacturers to place opioid drugs on standard formulary offerings with preferred status; declining to

impose limits on their approval for use of opioids in exchange for payments and fees from manufacturers; electing not to (and/or failing to) provide controls against diversion in their PBM services; and violating the Controlled Substances Act, and State controlled substances and pharmacy laws and regulations, by failing to detect and guard against diversion when dispensing opioids, and "cocktails" of opioids and other drugs, through their mail order pharmacies, and in their provision of PBM services. Their conduct caused prescriptions and sales of opioids to skyrocket, and Defendants failed to limit their use even as evidence of the epidemic mounted, including Plaintiff's Community, flooding Plaintiff's Community with opioids and facilitating and encouraging the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiff's Community and its residents.

720. Defendants knew, or were substantially certain, or reasonably should have known that their intentional and/or negligent, unreasonable, reckless, and/or unlawful conduct would and did cause opioids to be used and possessed illegally and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental and unreasonable effect upon the public health, welfare, safety, peace, comfort, and convenience of Plaintiff and the residents of Plaintiff's Community.

721. Defendants' conduct has injuriously affected rights common to the general public, specifically including the rights of the people of Plaintiff's Community to public health, safety, peace, comfort, and convenience. The public nuisance caused

by Defendants' actions has caused substantial annoyance, inconvenience, and injury to the public.

722. The interference is unreasonable because Defendants' nuisance-creating conduct:

(a) Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience;

(b) At all relevant times was and is proscribed by state and federal laws and regulations; and/or

(c) Is of a continuing nature and, as Defendants know, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

723. The significant interference with rights common to the general public is described in detail herein and in Plaintiff's Complaint (Doc. No. 1), and includes but is not limited to:

(a) The creation and fostering of an illegal, secondary market for prescription opioids;

(b) Easy access to prescription opioids by children and teenagers;

(c) A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;

(d) Infants being born dependent on, or addicted to, opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;

(e) Employers having lost the value of productive and healthy employees; and

(f) Increased costs and expenses for Plaintiff relating to healthcare services, law enforcement, the criminal justice system, social services, and education systems.

724. Defendants knowingly, intentionally, recklessly, negligently, and/or unlawfully pushed as many opioids, and "cocktails" of opioids and other drugs, onto the market as possible, fueling addiction to and diversion of these powerful narcotics, resulting in increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiff's Community, a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's Community, and direct costs to Plaintiff and the residents of its community.

725. Defendants are liable for creating the public nuisance because the intentional and/or negligent, and unreasonable and/or unlawful conduct of each Defendant was a substantial factor in producing the public nuisance and harm to Plaintiff.

726. At all relevant times, Defendants were (or reasonably should have been) aware of, and understood, their legal obligations under the federal Controlled Substances Act (21 U.S.C. § 801, *et seq.*), the Missouri Comprehensive Drug Control Act (Mo. Rev. Stat. §§ 195.005, *et seq.*), and applicable Missouri pharmacy laws and regulations regarding the dispensing of prescription opioids.

727. In their sale and dispensation of opioids, and "cocktails" of opioids and other drugs, in the State and in Plaintiff's Community, Defendants violated federal law, including, but not limited to, 21 U.S.C.A. §§ 829, 841, 842 and 21 C.F.R. §§ 1301.71, 1306.04, 1306.06, and Missouri law, including, but not limited to, Mo. Rev. Stat. § 195.030, Mo. Rev. Stat. § 195.040, Mo. Rev. Stat. § 338.210, Mo. Rev. Stat. § 338.250, Mo. CSR 2220-2.010, Mo. CSR 2220-2.011, Mo. CSR 2220-2.013, and

Mo. CSR 2220-2.195.and regulations Defendants' violations of these laws were committed knowingly and/or negligently and recklessly.

728. Defendants' intentional (and/or negligent and reckless), unlawful, and unreasonable conduct that created, continued, and/or maintained the public nuisance in Plaintiff's Community, for which the gravity of the harm outweighs the utility of the conduct, is described herein and in Plaintiff's its Verified Complaint dated June 5, 2019 (1:19-op-45853, Doc #: 1-5) and includes, but is not limited to:

(a) Knowingly and intentionally (and/or negligently and recklessly) colluding with the opioid manufacturers in deceptive marketing schemes that were designed to, and successfully did, change the perception of opioids and cause opioid prescribing and sales to skyrocket;

(b) Knowingly and intentionally (and/or negligently and recklessly) facilitating the increased use of opioids by giving opioids unwarranted preferred formulary status in standard offerings in exchange for profiting from payments from the opioid manufacturers;

(c) Intentionally (and/or negligently and recklessly) maintaining preferred formulary status for OxyContin and other highly abused opioids in standard offerings, despite knowing, or being substantially certain, from their own extensive data, that addiction, abuse, and illegitimate prescribing of such drugs were rampant;

(d) Deliberately (and/or negligently and recklessly) electing not to undertake timely actions utilizing their real-time data that would have drastically reduced the inappropriate prescribing and dispensing of Opioids, such as requiring prior authorization, step therapy, limiting days of supply, or excluding OxyContin from its standard formulary offerings;

(e) Deliberately (and/or negligently and recklessly) electing not to impose prior authorization requirements or limits on the availability of opioids in its standard formulary offerings in exchange for payments from the opioid manufacturers;

(f) Deliberately (and/or negligently and recklessly) electing not to maintain adequate safeguards to dispense opioids in a safe and effective manner and to maintain effective controls against diversion of opioids through their mail-order pharmacies; and

(g) Deliberately (and/or negligently and recklessly) electing not to report suspicious prescribers and pharmacies.

729. When Defendants engaged in this conduct, they knew, or were substantially certain, or reasonably should have known, that, *inter alia*: (i) increasing the availability of opioids would increase the number of opioids that would be abused, misused, and diverted into the illegal, secondary market and would be obtained by persons with criminal purposes; (ii) the marketing by manufacturers with which they colluded was deceptive and that Defendants' conduct served to increase opioid sales; (iii) many of the opioid prescriptions they dispensed, or facilitated the dispensing of, were not issued for a legitimate medical purpose and were likely to be diverted; and (iv) by failing to act reasonably and lawfully with respect to the sale and dispensing of opioids, and "cocktails" of opioids and other drugs, and by participating in the false marketing of opioids, in Plaintiff's Community, diversion and the associated harms and resulting interference with public health, safety, and welfare would occur.

730. At all relevant times, Defendants knew or reasonably should have known that opioids were dangerous because, *inter alia*, these drugs are defined under federal and state law, and are generally recognized, as substances posing a high potential for abuse, addiction, and death.

731. Indeed, prescription opioids are essentially medical grade heroin. Defendants' wrongful and unreasonable conduct of pushing as many opioids, and

"cocktails" of opioids and other drugs, onto the market as possible led directly to the public nuisance and harm to Plaintiff—exactly as would be expected when medical-grade heroin in the form of prescription opioids flood the community and are diverted into an illegal, secondary market.

732. It was reasonably foreseeable to Defendants that their conduct would result in the public nuisance and unreasonable harm to Plaintiff described herein.

733. Defendants owe Plaintiff and the public a duty to employ reasonable standards of care in the sale, delivery, dispensing, promotion, and gatekeeping control of the supply of highly addictive, dangerous opioids. This includes a duty to not create a foreseeable risk of harm or injury.

734. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in selling, delivering, dispensing, promoting, and gatekeeping control of the supply of highly addictive and dangerous opioids requires a high degree of care and places them in a position of great trust and responsibility. Their duty cannot be delegated.

735. Defendants, by promoting opioid over-use and by facilitating access to opioids through their standard formulary and UM offerings and their mail-order pharmacies, set in motion a force that created an unreasonable and foreseeable risk of harm for Plaintiff and its community.

736. Defendants also undertook and assumed a duty to create standard formulary and UM offerings based on the health and safety of the public and of the lives covered by the benefit plans that were their clients. *See* Restatement (Second)

of Torts § 324A. Defendants represented to the public, as well as to their clients, that they were structuring their standard formulary and UM offerings based on the health and safety of the public and the lives their clients insured, when in fact they were doing the exact opposite and doing it to maximize their own revenue in concert with the opioid manufacturers. Defendants knew, at the time that they made these representations to the public and to their clients, that they would not base their formulary and UM offerings on the health and safety of the covered lives involved, nor of the public, but rather that they would make, and were already making, formulary and utilization management decisions designed solely (or at least primarily) to increase profits to Defendants.

737. Defendants undertook to render services which Defendants should have recognized (and in fact did know) were necessary for the protection of persons, including the public, residents of Plaintiff's Community, and Plaintiff, and failed to exercise reasonable care such that it increased the risk of harm to the public, residents of Plaintiff's Community, and the Plaintiff. In so undertaking, Defendants assumed a duty to the public, residents of Plaintiff's Community, and the Plaintiff.

738. Defendants knew or reasonably should have known of the over-use and over-supply of opioids because of their access to claims and other data which they developed and maintained. Defendants also had the ability to curtail the over-use and over-supply of prescription opioids because of their unique gatekeeping function in the pharmaceutical supply chain. Yet, despite this knowledge and ability, Defendants

refused and failed to take necessary and appropriate actions to prevent the harms which were the foreseeable consequence of their failures, actions, and inactions.

739. Defendants, having facilitated and set in motion the over-use and over-supply of opioids, had a duty to use reasonable care to prevent and curtail the spreading opioid crisis.

740. Defendants breached this duty by failing to exercise reasonable care or skill with respect to their opioid-related conduct. Collectively and individually, Defendants made highly addictive prescription opioids available to the marketplace with the knowledge that they were likely being used for non-medical purposes and/or posed an inherent danger especially to patients who were using opioids for chronic pain not associated with active cancer, end-of-life or palliative care. Defendants knew or reasonably should have known that their breach would foreseeably cause harm to Plaintiff and local governments nationwide.

741. Defendants were negligent in failing to abide their duties to conduct themselves with the requisite care and skill and faithfulness.

742. Defendants placed their profit motives above their legal duties and enabled, encouraged, and caused the over-use and over-supply of opioids.

743. Defendants are highly sophisticated and knowledgeable actors in the health care marketplace, well informed of the highly addictive nature of prescription opioids and likelihood of foreseeable harm to communities from prescription opioid addiction and diversion. Defendants breached their duties when they failed to act with reasonable care in their respective roles, roles which positioned each of them to

help abate the opioid epidemic if they elected to use their power for good, instead of profit.

744. Violating these duties poses distinctive and significant dangers to Plaintiff.

745. Defendants knew or in the exercise of reasonable diligence should have known under the circumstances of this case that the public nuisance and the harms suffered by Plaintiff were the reasonably foreseeable consequences of Defendants' failures, actions, and inactions.

746. It was also reasonably foreseeable to Defendants that their conduct would create a new secondary market for opioids—providing both the supply of narcotics to sell and the demand of addicts to buy them. The result of Defendants' deceptive and improper conduct is not only an explosion of prescription opioids on the black market, but also—predictably—a marked increase in the availability of heroin and synthetic opioids.

747. The health, safety, and welfare of the citizens of Plaintiff's Community, including those who use, have used, or will use opioids, as well as those affected by opioid users, is a matter of great public interest and legitimate concern to the citizens and residents of Plaintiff's Community. It was reasonably foreseeable to Defendants that the burden of the opioid crisis would fall to communities like Plaintiff in the form of social and economic costs.

748. The public nuisance created by Defendants' intentional, negligent, and/or reckless conduct is substantial and unreasonable. It has caused and continues

to cause significant harm to Plaintiff and the residents of Plaintiff's Community, and the harm inflicted greatly outweighs any offsetting benefit.

749. The injuries to Plaintiff would not have happened in the ordinary course of events had Defendants exercised the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business in the sale, delivery, dispensing, promotion, and gatekeeping control of opioids.

750. Defendants' conduct is widespread and persistent and creates substantial and ongoing harm. The harm inflicted outweighs any offsetting benefit. Defendants' conduct has caused deaths, serious injuries, and a severe disruption of public peace, health, order and safety. Defendants' ongoing and persistent misconduct is producing permanent and long-lasting damage.

751. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used in Plaintiff's Community. Because of Defendants' actions in using their unique position to increase the availability of opioids in the marketplace and inflate opioid sales, because of their collusion with manufacturers in the deceptive marketing of opioids, and because of Defendants' special position within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

752. Defendants had control over their conduct in and affecting Plaintiff's Community as is described herein, and that conduct has had an adverse effect on the

public. Defendants had sufficient control over, and responsibility for, the public nuisance they created. Defendants were in control of the "instrumentality" of the nuisance, namely the dissemination of prescription opioids, their collusion with manufacturers in promoting opioids, and standard formulary placement and drug utilization management offerings that increased utilization of opioids as described herein.

753. Plaintiff does not allege that the opioid drugs are inherently defective, nor that the FDA-approved warning labels are inadequate, and Plaintiff does not seek a remedy under theories of product defect or failure to warn.

754. Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

755. Defendants' scheme to optimize profits and opioid utilization regardless of the harm that was substantially certain to occur to Plaintiff's Community was done knowingly and intentionally and/or negligently and recklessly.

756. But for Defendants' actions, opioid use—and, ultimately, misuse and abuse—would not be as widespread as it is today, and the opioid epidemic that currently exists would have been averted or greatly curtailed.

757. As a direct and proximate cause of Defendants' intentional and/or negligent and reckless conduct creating or assisting in the creation of a public nuisance, Plaintiff, its community, and its residents have sustained and will continue to sustain substantial injuries.

758. Plaintiff has authority under Missouri common law to abate a public nuisance.

759. Plaintiff brings this action to promote the public welfare, for the benefit of all who live in and around Plaintiff's Community, the public generally, and the State.

760. In addition, Plaintiff has sustained injury to its property and resources because of the public nuisance described herein.

761. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

762. Defendants' misconduct alleged in this case is ongoing and persistent, as is the nuisance to which they substantially contributed.

763. As a direct and proximate result of Defendants' intentional and/or negligent and reckless conduct and the public nuisance created by Defendants, Plaintiff has incurred, and will continue to incur, excessive costs to treat the opioid epidemic in its community including, but not limited to, increased costs of police, emergency, health, prosecution, corrections, rehabilitation, and other services. These costs are over and above Plaintiff's ordinary public services.

764. As a direct and proximate result of Defendants' intentional and/or negligent and reckless conduct and the public nuisance created by Defendants, public

resources are being unreasonably consumed in efforts to address the opioid epidemic, thereby eliminating available resources which would otherwise be used to serve the public at large in Plaintiff's Community.

765. Plaintiff seeks to abate the nuisance created by Defendants' unreasonable, unlawful, intentional and/or negligent, reckless, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.

766. The public nuisance in Plaintiff's Community—*i.e.*, the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be prevented. However, Defendants lack the infrastructure and expertise needed to abate the public nuisance they created, contributed to, and/or maintained in Plaintiff's Community. Defendants' conduct – including their lack of regard for the well-being of the citizens of Plaintiff's Community by elevating their own business interests and profit over the safety and health of the communities in which they marketed, promoted, dispensed, and sold opioids – also renders them unfit to oversee the abatement of the public nuisance they created, contributed to, and/or maintained.

767. Plaintiff seeks a judgment that Defendants fund the abatement of the ongoing public nuisance caused by their unreasonable, unlawful, intentional and/or negligent, reckless, ongoing, continuing, and persistent actions and omissions and their substantial and unreasonable interference with rights common to the general public.

768. Each Defendant created or assisted in creating the opioid epidemic, and each Defendant is jointly and severally liable for its abatement. Furthermore, each Defendant should be enjoined from continuing to create, perpetuate, or maintain said public nuisance in Plaintiff's Community. Additionally, Defendants should compensate Plaintiff for the funds it has expended and continues to expend for increased costs of, *inter alia*, social services, health systems, law enforcement, judicial system, and treatment facilities.

769. Plaintiff has suffered, and will continue to suffer, unique harms as described herein, which are of a different kind and degree than those suffered by the citizens of the State and Plaintiff's Community at large. These are harms that can only be suffered by Plaintiff.

770. Plaintiff is acting in its governmental capacity to vindicate the rights of the public and abate a public nuisance within its community. Its claims are not based upon or derivative of the rights of others.

771. The tortious conduct of Defendants was a substantial factor in producing harm to Plaintiff.

772. Plaintiff has suffered an indivisible injury as a result of the tortious conduct of Defendants.

773. Defendants' conduct was intentional, willful, wanton and/or reckless was directed at the public generally, constituted a gross and wanton fraud upon the public, and/or constituted gross negligence. Defendants acted with conscious

disregard of the rights of the Plaintiff and its residents. For this reason, Plaintiff seeks to recover punitive/exemplary damages.

774. Defendants' conduct was wanton, in that it was committed with reckless disregard of the Plaintiff's and public's rights or the consequences of said conduct.

775. Defendants acted with malice. Defendants specifically intended to cause substantial injury or harm to Plaintiff because they either desired to cause the consequences of their actions or omissions, or believed that the consequences were substantially certain to result from their actions or omissions. Specifically, Defendants knew that their conduct was resulting in, or was substantially certain to result in, an unreasonable and substantial interference with the public health, welfare, and safety in Plaintiff's Community.

776. Defendants' conduct was fraudulent. Defendants acted in concert with opioid manufacturers to promote false and fraudulent messaging about the treatment of pain and the addictive nature of opioids. Defendants also created the false and misleading impression to regulators, prescribers, their clients, and the public, that they rigorously carried out their legal duties, including their duty to implement effective controls against diversion and to exercise due diligence to prevent the dispensing of opioid prescriptions that are illegitimate and/or likely to be diverted. Defendants further created the false impression that they worked voluntarily to prevent opioid abuse, misuse, oversupply, and diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

777. Defendants' actions and omissions were grossly negligent. They had actual, subjective awareness that, viewed objectively from their viewpoint at the time, their conduct involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Defendants knew of the dangerous and addictive nature of prescription opioids and also knew the risks associated with the oversupply and diversion of such drugs. Yet they nevertheless proceeded with conscious and/or reckless indifference to the rights, safety, or welfare of Plaintiff and its citizens by and through their conduct described herein. For this reason, Plaintiff seeks to recover punitive/exemplary damages.

778. Plaintiff seeks all legal and equitable relief as allowed by State law for the intentional and/or negligent creation of a public nuisance, including, *inter alia*, injunctive relief, abatement, compensatory and exemplary/punitive damages, and all other damages allowed by law to be paid by Defendants, attorneys' fees and costs, pre- and post-judgment interest, and such other relief as this Court deems appropriate.

SECOND CLAIM FOR RELIEF—VIOLATION OF FEDERAL CIVIL RICO, 18 U.S.C. 1961, *ET SEQ.;* 1964(c)
(Brought by Plaintiff Against All Defendants)

779. Plaintiff repeats, re-alleges, and incorporates each and every allegation set forth in all other paragraphs of these Supplemental and Amended Allegations to the Complaint, as well as each and every allegation set forth in all other paragraphs of its Complaint (Doc. No. 1), as if fully set forth herein, and further alleges as follows:

780. At all relevant times, Express Scripts and Optum were each a "person" under 18 U.S.C. § 1961(3) because they were both capable of holding, and do hold, legal or beneficial interests in property.

781. As alleged more fully herein, the PBM Defendants formed an association-in-fact enterprise with each of the Opioid Enterprise Manufacturers, described above as the Formulary & UM Enterprise, for the purpose of carrying out a fraudulent scheme and felonious possession and dispensing of controlled substances to maximize profits for themselves and the Opioid Enterprise Manufacturers from increasing sales of prescription opioids through unfettered and preferential formulary access without UM in the PBM Defendants' standard offerings, despite the PBM Defendants' promises, representations and contractual obligations to take actions, including through cDUR, formulary decisions and UM decisions that were in their clients' best interests, to ensure safe and medically appropriate opioids were being dispensed, and to address opioid abuse, misuse and diversion.

782. As alleged more fully herein, the Formulary & UM Enterprise consisted of personal business relationships formed through contractual negotiations over decades and participation in and through the PCMA and other informal coalitions and working groups. Evidence of the existence of the Formulary & UM Enterprise can be found in the way in which each PBM Defendant took nearly identical action towards formulary and UM offerings, in the research they performed for the Opioid Enterprise Manufacturers, the contracts they negotiated with the Opioid Enterprise Manufacturers that gave them preferential formulary positions prohibited the

implementation of UM, the research that each PBM Defendant performed for Opioid Enterprise Manufacturers, pull-through marketing and PBM data exchange, failure to comply with the dispensing requirements of the CSA and Missouri law, and interactions through PCMA and other informal coalitions..

783. At all relevant times, the Formulary & UM Enterprise (a) had an existence separate and distinct from each of the members; (b) was separate and distinct from the pattern of racketeering in which the members engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the members; (d) was characterized by interpersonal business relationships among the members; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as continuing units.

784. Each member of the Formulary & UM Enterprise conducted, and participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding profits.

785. The PBM Defendants carried out, or attempted to carry out, a scheme to defraud by knowingly conducting and participating in the conduct of the Formulary & UM Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that made use of the mail and wire facilities in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

786. The PBM Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts

of racketeering activity that the Formulary & UM Enterprise members committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Formulary & UM Enterprise members' regular use of the facilities, services, distribution channels, and employees of the Formulary & UM Enterprise. The PBM Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

787. PBM Defendants also conducted and participated in the conduct of the affairs of the Formulary & UM Enterprise through a pattern of racketeering activity by the felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in controlled, punishable under any law of the United States.

788. PBM Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 841 makes it unlawful for any person to knowingly or intentionally manufacture, distribute, or dispense, or possess with intent to manufacture, distribute or dispense, a controlled substance except as authorized by Subchapter I of the CSA. A violation of § 841 in the case of controlled substances on Schedule II is punishable by not more than 20 years of imprisonment, or not less than 20 years imprisonment if death or seriously bodily injury results from the use of such substance.[272] Similarly, a violation of § 841 in the case of controlled substances on Schedule III is punishable by not more than 10 years

[272] 21 U.S.C. § 841(b)(1)(C).

imprisonment, or not less than 15 year imprisonment if death or seriously bodily injury results from the use of such substance.[273] Similarly, a violation of § 841 in the case of controlled substances in Schedule IV is punishable by note more than 5 years imprisonment.[274] All three violations of § 841 are felonies.

789. Each of PBM Defendants' mail order pharmacies is a registrant as defined in the CSA. Their status as registrants imposes obligations on them to ensure that they only dispense "to the extent authorized by their registration and in conformity with the [CSA].[275]

790. PBM Defendants registered their mail order pharmacies with the DEA to dispense Schedule II-V controlled substances. Their DEA registrations only authorized Defendants' owned pharmacies to "dispense" controlled substances, which "means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner."[276]

791. The Formulary & UM Enterprise's predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

(a) Mail Fraud: The Formulary & UM Enterprise violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme of the Formulary & UM Enterprise.

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[273] 21 U.S.C. § 841(b)(1)(E).

[274] 21 U.S.C. § 851(b)(2).

[275] 21 U.S.C. § 822(b).

[276] 21 U.S.C. § 802(10); 21 U.S.C. § 829(a)-(b) (stating no Schedule II, III or IV drug may be dispensed without the written prescription of a practitioner, and that no Schedule V drug may be dispensed other than for a medical purpose); *accord* 21 U.S.C. § 823(f)

(b) Wire Fraud: The Formulary & UM Enterprise violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme of the Formulary & UM Enterprise.

(c) Felony Controlled Substance Violations: The PBM Defendants violated 21 U.S.C. § 841 by knowingly or intentionally possessing and dispensing controlled substances for reasons and purposes not authorized by the Controlled Substance Act.

792. The Formulary & UM Enterprise conducted their pattern of racketeering activity in this jurisdiction and throughout the United States.

793. The Formulary & UM Enterprise aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses, and the 21 U.S.C. § 841 offense.

794. The members of the Formulary & UM Enterprise, with knowledge and intent, agreed to the overall objective of the Formulary & UM Enterprise, including the fraudulent scheme and felonious possession and dispensing of controlled substances, and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing, distributing, and dispensing prescription opioids.

795. Indeed, for the Formulary & UM Enterprise's fraudulent scheme to work, each member of the Formulary & UM Enterprise had to agree to implement their necessary portion of the Formulary & UM Enterprise's activities in the manner alleged above.

796. As alleged more fully herein, the Formulary & UM Enterprise engaged in a pattern of related and continuous predicate acts for years. The predicate acts were each conducted with the common purpose of obtaining significant monies and

revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

797. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiff's business and property, while simultaneously generating billion-dollar revenue and profits for the Formulary & UM Enterprise. The predicate acts were conducted by members of the Formulary & UM Enterprise and in furtherance of its fraudulent scheme.

798. The pattern of racketeering activity alleged more fully herein, and the Formulary & UM Enterprise are separate and distinct from each other. Likewise, the PBM Defendants are distinct from the Formulary & UM Enterprise.

799. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

800. Many of the precise dates of the Formulary & UM Enterprise's actions at issue here have been hidden by the PBM Defendants and the members of the Formulary & UM Enterprise and cannot be alleged without complete access to the PBM Defendants' books, records, and dispensing data. Indeed, an essential part of the successful operation of the Formulary & UM Enterprise alleged herein depended upon secrecy.

801. It was foreseeable to the PBM Defendants and members of the Formulary & UM Enterprise that Plaintiff would be harmed when they engaged in

the fraudulent scheme that forms the common purpose of the Formulary & UM Enterprise and the pattern of racketeering activities alleged herein.

802. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

803. The Formulary & UM Enterprise members' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property.

804. The Formulary & UM Enterprise members' pattern of racketeering activity logically, substantially and foreseeably has caused an opioid epidemic. Plaintiff was injured by the Formulary & UM Enterprise's pattern of racketeering activity and the opioid epidemic that its members created through their actions.

805. Members of the Formulary & UM Enterprise knew that the prescription opioids at the center of their pattern of racketeering activity were extremely dangerous, highly addictive, prone to diversion, abuse and misuse, and often cause overdose and death. They were also aware that placing those drugs in favorable formulary positions with UM controls in place would grow the market for prescription opioids through increased prescribing, dispensing and sales. They were also aware that the growth in prescribing, dispensing and sales would be driven, in large part, by oversupply, addiction, and misuse and abuse. Members of the Formulary & UM Enterprise also knew that the oversupply, addiction, misuse and abuse would result in the writing of illegitimate prescriptions about which the PBM Defendants' mail-order pharmacies would need to conduct due diligence or refuse to fill.

806. Nevertheless, members of the Formulary & UM Enterprise engaged in a scheme of deception, which utilized the mail and wires as part of their fraud, in order to increase prescribing of prescription opioids, and providing the Opioid Enterprise Manufacturers' drugs unfettered formulary access without limits from UM in the PBM Defendants' standard offerings. Members of the Formulary & UM Enterprise also engaged in felonious possession and dispensing of controlled substances by filling prescriptions without performing due diligence and failing to refuse to fill prescriptions, thereby providing the Formulary & UM Enterprise with unfettered and illegal possession and dispensing by PBM Defendants' mail order pharmacies.

807. Plaintiff was and continues to be damaged in its business and property by reason and as a result of the Defendants' conduct of the Enterprise through the pattern and practice of racketeering activity described herein, which was a logical, direct, foreseeable and substantial cause of the opioid epidemic.

808. The predicate acts and pattern of racketeering activity by the members of the Formulary & UM Enterprise has injured Plaintiff in the form of substantial losses of money and property that were a logical, direct, and foreseeable substantial contributing cause of the opioid epidemic.

809. Specifically, Plaintiff's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

(a) [Losses caused by purchasing and/or paying reimbursements for the Formulary & UM Enterprise Defendants' prescription opioids, that Plaintiff would not have paid for or purchased but for the Formulary & UM Enterprise Defendants' conduct;

(b) Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

(c) Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

(d) Costs associated with providing police officers, firefighters, and emergency and/or first responders with naloxone, an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

(e) Costs associated with emergency response by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

(f) Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

(g) Loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's Community;

(h) Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

(i) Losses caused by diminished property values in the form of decreased business investment and tax revenue.

810. Plaintiff's injuries were proximately caused by the PBM Defendants' racketeering activities because they were a logical, substantial, and foreseeable cause of Plaintiff's injuries. But for the opioid-addiction epidemic created by the PBM Defendants' conduct, Plaintiff would not have lost money or property.

811. Plaintiff's injuries were directly caused by the pattern of racketeering activities by the members of the Formulary & UM Enterprise.

812. Plaintiff is most directly harmed and there are no other Plaintiffs better suited to seek a remedy for the economic harms at issue here.

813. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages; treble damages; equitable and/or injunctive relief in the form of court supervised corrective communication, actions and programs; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest, including, *inter alia*:

(a) Actual damages and treble damages, including pre-suit and post-judgment interest;

(b) An order enjoining any further violations of RICO;

(c) An order enjoining any further violations of any statutes alleged to have been violated in this Complaint;

(d) An order enjoining the commission of any tortious conduct, as alleged in this Complaint;

(e) An order enjoining any future marketing or misrepresentations;

(f) An order enjoining future decisions by the PBM Defendants to prioritize rebates and profits over patient safety and proper, clinically based, decision making regarding the formulary status, prior authorization, step therapy or utilization management measures related to prescription opioids;

(g) An order enjoining the PBM Defendants' mail order pharmacy from dispensing prescriptions without conducting proper due diligence and documenting that due diligence before dispensing prescriptions;

(h) An order compelling Defendants to make corrective advertising statements that shall be made in the form, manner and duration as determined by the Court;

(i) An order enjoining any future lobbying or legislative efforts regarding the manufacture, marketing, distribution, prescription, or use of opioids;

(j) An order requiring the PBM Defendants to disclose publicly all documents, communications, records, data, information, research or studies concerning the health risks or benefits of opioid use;

(k) An order establishing a national foundation for education, research, publication, scholarship, and dissemination of information regarding the health risks of opioid use and abuse to be financed by the PBM Defendants in an amount to be determined by the Court;

(l) An order enjoining any diversion of opioids or any failure to monitor, identify, investigate, report and halt suspicious prescribing, dispensing, abuse, or diversion of opioids;

(m) An order requiring all PBM Defendants to publicly disclose to law federal and state endorsement all documents, communications, records, information, or data, regarding any prescriber, facility, pharmacy, clinic, hospital, manufacturer, distributor, person, entity or association regarding prescribing, dispensing, abuse, or diversion of opioids;

(n) An order divesting each PBM Defendant of any interest in, and the proceeds of any interest in, the Formulary & UM Enterprise, including any interest in property associated therewith;

(o) Dissolution and/or reorganization of any trade industry organization, or any other entity or association associated with the Formulary & UM Enterprise identified in this Complaint, as the Court sees fit;

(p) Dissolution and/or reorganization of any Defendant named in this Complaint as the Court sees fit;

(q) Suspension and/or revocation of the license, registration, permit, or prior approval granted to Defendants, entities, associations or enterprises named in the Complaint regarding the prescribing of opioids;

(r) Forfeiture as deemed appropriate by the Court; and

(s) Attorney's fees and all costs and expenses of suit.

THIRD CLAIM FOR RELIEF—NEGLIGENCE AND GROSS NEGLIGENCE
(Brought by Plaintiff against All Defendants)

814. Plaintiff repeats, re-alleges, and incorporates each and every allegation set forth in all other paragraphs of these Supplemental and Amended Allegations to the Complaint, as well as each and every allegation set forth in all other paragraphs of its Complaint (Doc. No. 1), as if fully set forth herein, and further alleges as follows:

815. Defendants owe Plaintiff a duty to employ reasonable standards of care in the sale, delivery, dispensing, promotion, and gatekeeping control of the supply of highly addictive, dangerous opioids. This includes a duty to not create a foreseeable risk of harm or injury.

816. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in selling, delivering, dispensing, promoting, and gatekeeping control of the supply of highly addictive and dangerous opioids requires a high degree of care and places them in a position of great trust and responsibility. Their duty cannot be delegated.

817. Defendants, by promoting opioid over-use and by facilitating access to opioids through their standard formulary and utilization management offerings and their mail order pharmacies, set in motion a force that created an unreasonable and foreseeable risk of harm and peril for Plaintiff and its community.

818. Defendants also undertook and assumed a duty to create formulary and UM offerings based on the health and safety of the public and of the lives covered by the benefit plans that were their clients. See Restatement (Second) of Torts § 324A Defendants represented to the public, as well as to their clients, that they were

structuring formulary and UM offerings based on the health and safety of the public and the lives their clients insured, when in fact they were doing the exact opposite and doing it to maximize their own revenue in concert with the opioid manufacturers. Defendants knew, at the time that they made these representations to the public and to their clients, that they would not base their formulary and their UM offerings on the health and safety of the covered lives involved, nor of the public, but rather that they would structure, and were already structuring, formulary and UM offerings solely (or at least primarily) to increase profits to Defendants.

819. Defendants undertook to render services which Defendants should have recognized (and in fact did know) were necessary for the protection of persons, including the public, residents of Plaintiff's Community, and Plaintiff, and failed to exercise reasonable care in such a manner that Defendants increased the risk of harm to the public, residents of Plaintiff's Community, and the Plaintiff. In so undertaking, Defendants assumed a duty to the public, residents of Plaintiff's Community, and the Plaintiff.

820. Defendants had actual or at the very least constructive knowledge of the overuse and oversupply of opioids because of their access to claims and other data which they developed and maintained. Defendants also had the ability to curtail the overuse and oversupply of prescription opioids because of their unique gatekeeping function in the pharmaceutical supply chain. Yet, despite this knowledge and ability, Defendants refused and failed to take necessary and appropriate actions to prevent

the harms which were the foreseeable consequence of their failures, actions and inactions.

821. Defendants, having facilitated and set in motion the over-use and over-supply of opioids, had a duty to use reasonable care to prevent and curtail the spreading opioid crisis.

822. Defendants breached this duty by failing to exercise reasonable care or skill with respect to their opioid-related conduct. Collectively, and individually, Defendants made highly addictive prescription opioids available to the marketplace with the knowledge that they were likely being used for non-medical purposes and/or posed an inherent danger especially to patients who were using opioids for chronic pain not associated with active cancer, end-of-life or palliative care. Defendants knew or reasonably should have known that their breach would foreseeably cause harm to Plaintiff.

823. Defendants were negligent in failing to abide their duties to conduct themselves with the requisite care and skill and faithfulness.

824. Defendants placed their profit motives above their legal duties and enabled, encouraged, and caused the over-supply and over-use of opioids.

825. Defendants are highly sophisticated and knowledgeable actors in the health care marketplace, well informed of the highly addictive nature of prescription opioids and likelihood of foreseeable harm to communities from prescription opioid addiction and diversion. Defendants breached their duties when they failed to act with reasonable care in their respective roles, roles which positioned each of them to

help abate the opioid epidemic if they elected to use their power for good, instead of profit.

826. A negligent and/or intentional violation of the Defendants' duties poses distinctive and significant dangers to the County.

827. At all times, Defendants each had the ability and obligation to control the opioid access and utilization that led to this human-made epidemic. Defendants controlled and were responsible for the operation of the instrumentality of the harm in this case—their promotion of opioid over-use and facilitation of access to opioids through their formularies and UM offerings and their mail order pharmacies. Defendants failed to take appropriate precautions to avoid injuries to Plaintiff caused by Defendants' failures, actions and inactions.

828. Defendants knew or in the exercise of reasonable diligence should have known under the circumstances of this case that the harms suffered by the Plaintiff were the reasonably foreseeable consequences of the Defendants' failures, actions and inactions.

829. Defendants' conduct also foreseeably created a new secondary market for opioids—providing both the supply of narcotics to sell and the demand of addicts to buy them. The result of Defendants' deceptive and improper conduct is not only an explosion of prescription opioids on the black market, but also—predictably—a marked increase in the availability of heroin and synthetic opioids.

830. The health, safety, and welfare of the citizens of Plaintiff's Community, including those who use, have used, or will use opioids, as well as those affected by

opioid users, is a matter of great public interest and legitimate concern to the citizens and residents of Plaintiff's Community and to Plaintiff. It was reasonably foreseeable to Defendants that the burden of the opioid crisis would fall to communities like Plaintiff in the form of social and economic costs. Defendants' negligence was a substantial factor in producing harm to Plaintiff and Plaintiff's Community.

831. Defendants controlled and were responsible for the operation of the instrumentality of the harm in this case – their promotion of opioid over-use and facilitation of access to opioids through their formularies and utilization management and mail order pharmacies. Defendants failed to take appropriate precautions to avoid injuries to Plaintiff and its community caused by Defendants' failures, actions and inactions.

832. As a direct and proximate result of Defendants' negligent conduct, Plaintiff has incurred, and will continue to incur, excessive costs to treat the opioid epidemic in Plaintiff's Community including, but not limited to, increased costs of police, emergency, health, prosecution, corrections, rehabilitation, and other services. These costs are over and above Plaintiff's ordinary public services.

833. As a proximate result of their failures, the Defendants have caused the County to incur excessive social and economic costs related to responding to the opioid crisis. These costs include but are not limited to, increased policing, medical, fire, and court services, lost tax revenues and lost productivity.

834. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably

expect to occur and is not part of the normal and expected costs of a local government's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

835. The injuries to Plaintiff would not have happened in the ordinary course of events had Defendants exercised the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of their business in the sale, delivery, dispensing, promotion, and gatekeeping control of opioids.

836. Plaintiff is asserting its own rights and interests and Plaintiff's claims are not based upon or derivative of the rights of others.

837. Plaintiff is entitled to recover compensatory damages as a result of Defendants' negligence, in an amount to be determined at trial.

838. Defendants' conduct was intentional, willful, wanton and/or reckless. They had actual, subjective awareness that, viewed objectively from their viewpoint at the time, their conduct involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Defendants knew of the dangerous and addictive nature of prescription opioids and also knew the risks associated with the oversupply and diversion of such drugs. Yet they nevertheless proceeded with the conscious indifference to the rights, safety, or welfare of Plaintiff and the residents of Plaintiff's Community by and through their conduct described herein. For this reason, Plaintiff seeks to recover punitive/exemplary damages.

839. As a result of Defendants' intentional, willful, wanton and/or reckless conduct described herein, Plaintiff seeks all legal and equitable relief as allowed by

Missouri law for negligence and gross negligence, including, *inter alia*, compensatory damages, including, *inter alia,* compensatory damages, treble, punitive, exemplary and/or otherwise enhanced damages to the full extent available under state law, and all damages allowed by law to be paid by Defendants, attorneys' fees and costs, pre- and post-judgement interest, and such other relief as this Court deems appropriate.

FOURTH CLAIM FOR RELIEF – CIVIL CONSPIRACY
(Brought by Plaintiff against All Defendants)

840. Plaintiff repeats, re-alleges, and incorporates each and every allegation set forth in all other paragraphs of these Supplemental and Amended Allegations to the Complaint, as well as each and every allegation set forth in all other paragraphs of its Complaint (Doc. No. 1), as if fully set forth herein, and further alleges as follows:

841. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in these Supplemental and Amended Allegations to the Complaint, as well as Plaintiff's Complaint (Doc. No. 1), including without limitation, all paragraphs addressing the PBM Defendants' agreements and concerted action with the opioid manufacturers, all paragraphs addressing Defendants' enterprises, and all racketeering counts. These allegations are specifically incorporated herein.

842. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, including without limitation, all paragraphs addressing Defendants' agreements and concerted action with the Opioid Manufacturers, all paragraphs addressing Defendants' enterprises, and all racketeering counts. These allegations are specifically incorporated herein.

843. As alleged in these paragraphs and throughout this Complaint, the Defendants and the opioid manufacturers engaged in concerted action to accomplish an unlawful objective, or to accomplish a lawful objective by unlawful means: the unfettered sale and dispensing of vast quantities of opioids in Plaintiff's Community without regard to patient safety, the impact on the community, or their obligations and duties under federal and state law. Each of the Defendants acted pursuant to an agreement, or meeting of the minds, with that common intent and purpose.

844. Defendants and co-conspirators committed numerous acts in furtherance of the conspiracy, as detailed throughout this complaint. Defendants and their co-conspirators, acting in concert and/or in conspiracy with one another, intentionally, unlawfully, and/or recklessly manufactured, marketed, distributed, and sold prescription opioids that Defendants knew, or reasonably should have known, would be improperly diverted, causing widespread distribution of prescription opioids in and/or to Plaintiff's Community. This resulted in addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiff's Community at the expense of the Plaintiff, a higher level of fear, discomfort and inconvenience within Plaintiff's Community, and direct and indirect costs to Plaintiff.

845. Specifically, opioid manufacturers contracted and agreed with PBMs, including the PBM Defendants, to coordinate unfettered formulary placement with no or limited UM measures regarding each opioid drug in the PBM Defendants' standard offerings, such that there would be as little an impediment as possible to opioid prescribing and dispensing. These contracts relied on an underlying fraudulent

scheme designed to ensure unfettered access to PBM formulary offerings. The opioid manufacturers understood that the PBM Defendants were going to operate on a fundamentally fraudulent basis. As alleged more fully herein, even though the PBM Defendants promised their clients they would take actions that would ensure the safety of opioid prescribing and dispensing, the PBM Defendants had no intention of taking actions regarding the opioid manufacturers' branded and generic drugs that would have ensured safety, because those actions would have dramatically reduced their receipt of rebates, revenue from opioid dispensing, and other fees. At the same time, the PBM Defendants operated their mail-order pharmacies in such a way that they did not stop obviously illegitimate prescriptions from being dispensed.

846. As detailed herein and in the Complaint (Doc. No. 1), the PBM Defendants and the opioid manufacturers committed numerous overt acts to further the conspiracy's objectives that were unlawful under federal and/or Missouri law.

847. At all relevant times, each Defendant was aware of the enterprise's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales, distributions, and prescriptions of opioids.

848. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, Defendants committed overt acts in furtherance of their conspiracy.

849. As an intended result of the intentional wrongful conduct as set forth herein, the PBM Defendants have profited and benefitted from the opioid epidemic they caused, thus harming Plaintiff's Community.

850. As a direct and proximate result of Defendants' and their co-conspirators the opioid manufacturers' intentional wrongful conduct, Plaintiff has incurred substantial costs including, but not limited to, law enforcement action for opioid-related to drug crimes, for addiction treatment, and other services necessary for the treatment of people addicted to prescription opioids, and the other harms alleged herein. Similarly, abating the vast societal harms Defendants and their co-conspirators caused will require extensive efforts and substantial resources. These costs and harms are addressed in more detail in the paragraphs addressing Plaintiff's racketeering and public nuisance counts. These allegations are specifically incorporated herein.

851. Plaintiff seeks to impute liability for the Plaintiff's other claims on the PBM Defendants for the wrongful conduct of their co-conspirators the opioid manufacturers and to hold the PBM Defendants jointly and severally liable for that conduct.

852. Additionally, as discussed above and in the Plaintiff's original Complaint (Doc. No. 1), the conduct of Defendants and their co-conspirators, the opioid manufacturers, was intentional, willful, wanton and/or reckless. For this reason, Plaintiff seeks to recover punitive/exemplary damages.

XIII. Prayer for Relief

WHEREFORE, Plaintiff respectfully requests the Court order the following relief, including:

(a) abatement of nuisance;

(b) actual damages;

(c) treble or multiple damages and civil penalties as allowed by statute;

(d) punitive damages;

(e) exemplary damages;

(f) disgorgement of unjust enrichment;

(g) equitable and injunctive relief in the form of Court-enforced corrective action, programs, and communications;

(h) forfeiture disgorgement, restitution and/or divestiture of proceeds and assets;

(i) attorneys' fees;

(j) costs and expenses of suit;

(k) pre- and post-judgment interest; and

(l) such other and further relief as this Court deems appropriate.

XIV. Jury Demand

Plaintiff demands a jury trial on all issues so triable.

December 15, 2023

Respectfully submitted,

Plaintiffs' Co-Lead Counsel

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Counsel for Plaintiff Lincoln County, MO

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 6th day of March, 2024, I have electronically filed the foregoing with the Clerk of Court using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court's CM/ECF System.

s/Peter H. Weinberger
Peter H. Weinberger